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National Patient Safety Agency

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Design for patient safety

A guide to the design of electronic infusion devices

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Postgraduate Art and Design

helen hamlyn centre

About this publication
This booklet is one of a series of design publications produced by the National Patient Safety Agency (NPSA). Other booklets in the series can be downloaded from: **www.nrls.npsa.nhs.uk/design**

Research and methodology
This publication is based on the results of a design research collaboration between the NPSA and the Royal College of Art Helen Hamlyn Centre (HHC), London.

The study was carried out over a one-year period by Sally Halls, a postgraduate specialist in medical design, working to a brief set out by the NPSA and the HHC. Existing design guidance was reviewed and consultations were undertaken with experts in graphic and information design, and design for patient safety. Technical support was provided throughout the project by David Cousins, Head of Safe Medication Practice and Medical Devices, NPSA.

A wide range of stakeholders contributed to the research, including patients, healthcare professionals, NHS organisations, the Medicines and Healthcare products Regulatory Agency (MHRA) and industry personnel.

Observational research was undertaken in clinical environments such as critical care areas, wards, and departments. The outcome was a design rationale to enhance patient safety and a fully illustrated set of design considerations with both good and bad examples.

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Foreword

As a user and purchaser of infusion devices I know and understand the issues related to infusion devices and the difference a well-designed device can provide with regards to ease of use, safety, training and efficiency.

The reverse is also true in that poorly designed devices can lead to confusion, errors and dissatisfaction amongst healthcare professionals.

This guide to the design of infusion devices is one of a series of design publications produced by the National Patient Safety Agency (NPSA), which also includes labelling and packaging of medicines.

This guide will provide manufacturers with guidance on what design features will improve the safe use of infusion devices in the future and will inform healthcare professionals and organisations when choosing and purchasing infusion devices as to what they need to consider for safety, efficiency and ease of use.

It is presented in four sections. The first is on hardware design and includes physical, ergonomic and electrical aspects, as well as the practical implications of loading, understanding the controls, display and alarm panel. It also makes recommendations for storage, maintenance and cleaning.

Section two provides guidance on software design and highlights the concerns related to configurations, medicine identification and drug libraries, and how they can improve safety if used and designed appropriately.

The last two sections cover administration sets and specialist devices such as Patient Controlled Analgesia and ambulatory devices.

The booklet uses clear diagrams to illustrate important design features for infusion devices; identifies key safety concerns users have with infusion devices; and sets out recommendations that were developed with the advisory group in a clinical context.

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The Royal Marsden Hospital Manual of Clinical Nursing Procedures. 2008.
Blackwell Publishing (Joint Editor)

Intravenous Therapy in Nursing Practice.
2008 Blackwell Publishing

Introduction

Fifteen million infusions are performed in the NHS every year. The vast majority are delivered safely. However, at least 700 unsafe incidents are reported each year, of which 19 per cent are attributed to user error.[1,2] In the 10 years between 1990 and 2000 there were 1,495 reports of incidents involving infusion devices in the UK.[3]

In 2004 the National Patient Safety Agency (NPSA) published a patient safety notice with recommendations on how to reduce the risk of patient safety incidents involving infusion devices.[1*]
The recommendations concerned:

- how purchasing decisions on infusion devices should be made in NHS organisations;
- the importance of evaluating the necessity for an infusion device before it is purchased;
- the need to reduce the range of infusion device types in use and, within each type, have agreed default configurations;
- the benefits of a establishing a centralised equipment library.

An evaluation report on this safety initiative piloted in six hospitals, has also been published.[4,5]

The NPSA still receives reports of around 250 patient safety incidents concerning the use of infusion devices each month. Although the vast majority of these reports have clinical outcomes of no harm or low harm to the patients, small numbers of reports have fatal and serious harm outcomes. *Design for patient safety: A guide to the design of electronic infusion devices* is the first guidance published that focuses on the safe design of infusion pumps and syringe drivers used in hospital and ambulatory care.

This publication illustrates how design can be used to change and make safer the use of infusion devices in practice. It is intended as a best practice guide to be used by infusion device developers in medical devices companies, as well as a reference guide for those involved in the procurement of infusion devices in the NHS.

The Department of Health and the Design Council report published in 2003, *Design for Patient Safety*, acknowledged that the use of design in other safety critical industries had produced significant improvements in safety, quality and efficiency.[6] The report recommended that a similar approach be taken within healthcare.

Human beings often make mistakes because the systems, tasks and products they work within are poorly designed. Effective design can deliver systems and products that are intuitive, simple to understand, simple to use and mistake-proofed.

Mistake-proofing is the use of process design to facilitate correct actions; make incorrect actions more difficult; make it easier to discover errors that occur; and make it possible to reverse or undo incorrect actions. Mistake-proofing tends to be inexpensive, very effective, and based on simplicity and ingenuity.[7]

* We use the term 'infusion device' in this publication to describe electronic volumetric infusion pumps and syringe drivers

Review of infusion device technology and evidence-based purchasing

The Centre for Evidence-based Purchasing (CEP) was part of the Policy and Innovation Directorate of the NHS Purchasing and Supply Agency (PASA). CEP will be transferring to the National Institute for Health and Clinical Excellence in 2010. CEP underpins purchasing decisions by providing objective evidence to support the uptake of useful, safe, innovative products and related procedures in health and social care.[8]

CEP buyers guides include one or more of the following elements:

- technology overview;
- market information;
- decision trees;
- comparative specifications;
- whole-life costing;
- cost/benefit analysis;
- adoption guidance;
- sustainable procurement;
- reliability analysis.

CEP have published buyers guide reviews on some infusion devices and more are planned in the future:

- Buyers guide. Ambulatory syringe drivers. CEP08046. December 2008.
- Buyers guide. Dose error reduction systems for infusion pumps. CEP08034. September 2008.
- Buyers guide. Portable pumps for home parenteral nutrition. CEP 08021. May 2008.
- Buyers guide. Insulin pumps. CEP 08004. February 2008.
- Evaluation report. Hospira Plum A+ volumetric infusion device. CEP 07014. October 2007.

The Bath Institute of Medical Engineering (BIME) also publish evaluation reports on infusion devices.[9]

The Medicines and Healthcare products Regulatory Agency (MHRA) also publishes Medical Device Alerts including ones on infusion devices.[10]

Purchasing for safety remains an important method to minimise risks and improve the safe use of infusion devices.

Independent evaluations by CEP and BIME provide important information that can be used by purchasing groups to select products that will be safer in practice. Infusion device manufacturers should work with these organisations to have their devices evaluated.

Two US reports support the importance of human factors and design considerations when purchasing infusion devices:

In a report from a Department of Anaesthesia and Critical Care in Chicago, the programming of infusion devices by clinicians showed no correlation between clinical experience and the ability to programme infusion pumps being considered for purchase.[11] The use of human factors methods to assist the selection of a new infusion pump was supported.

A report from the School of Nursing, University of Kansas, described reduced legibility of infusion pump screens due to small font size, reduced screen contrast and subdued lighting conditions in the clinical areas in which the pumps were being operated.[12] In some instances, nurses attached tape labels to the infusion pump to enhance and supplement the small screen display.

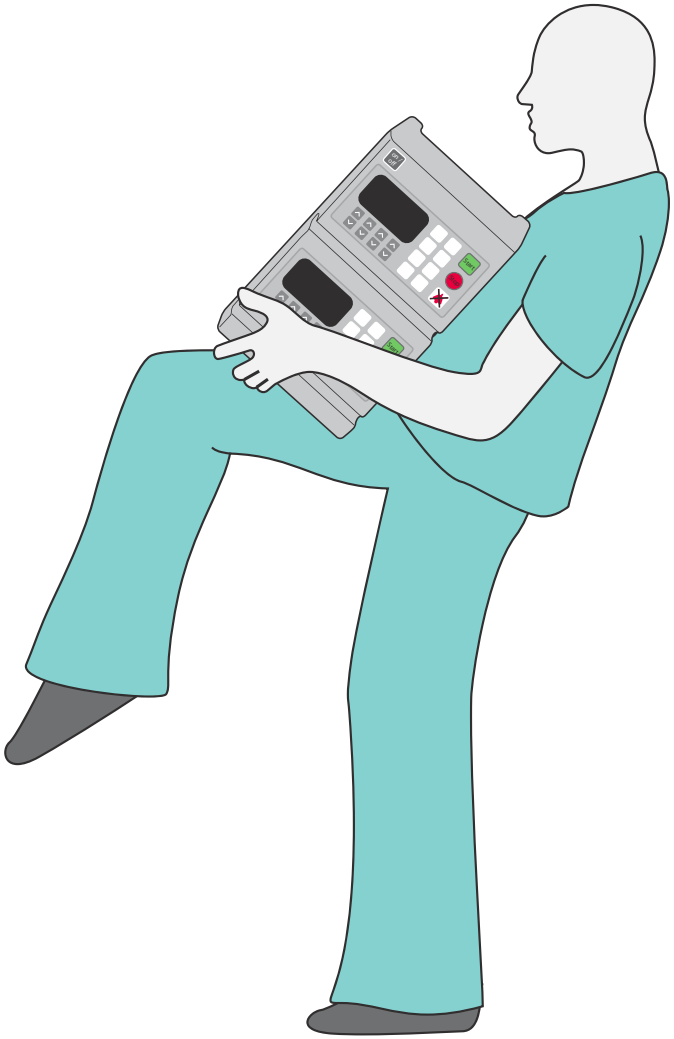
1

Hardware design

1.1 Physical dimensions

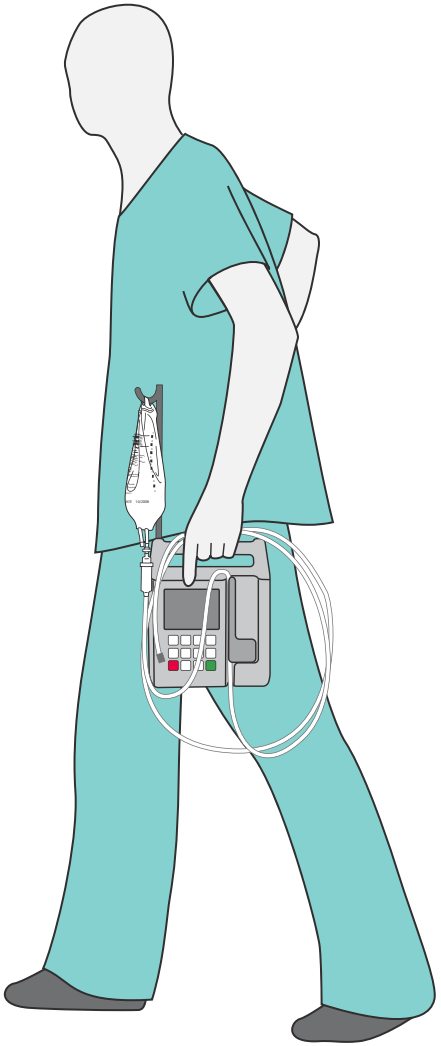
Issues

- Consideration is not given to the physical handling of the devices, leading to bulky and heavy equipment.
- The device size/shape is not suitable for its application.
- Devices are awkward to hold and handle.
- Infusion devices may be difficult to operate when the patient is being transported.



Recommendations

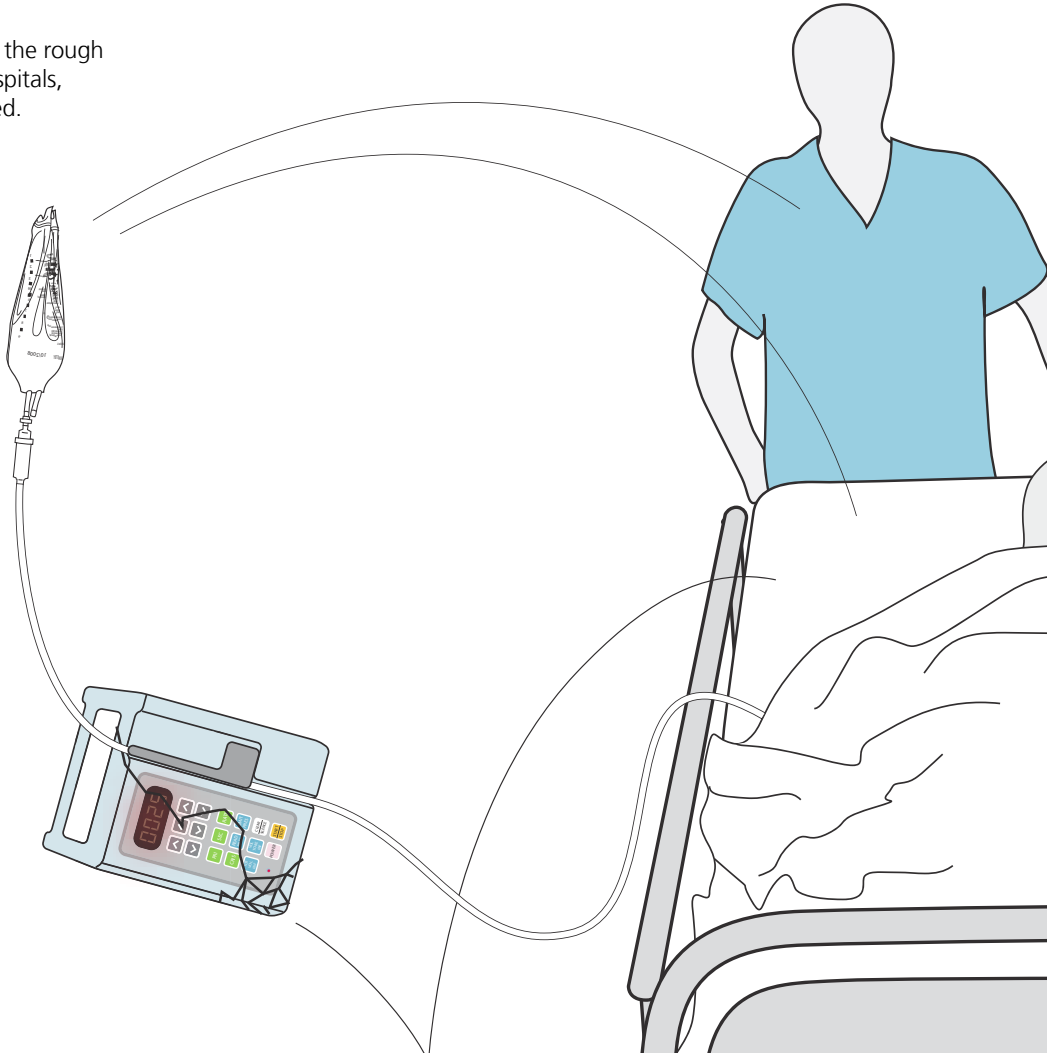
- Products should be developed with users, to ensure that they are of an appropriate size, shape and weight.
- Different sizes and shapes may be more suited to different applications. For example, an ambulatory device needs to be small and portable, but may be too small for general hospital ward use.
- Devices should have handles positioned to aid lifting and transport.
- Consider the addition of mini fluid stands or other methods to aid portability of infusion devices in circumstances such as patient transfer.



1.2 Durability

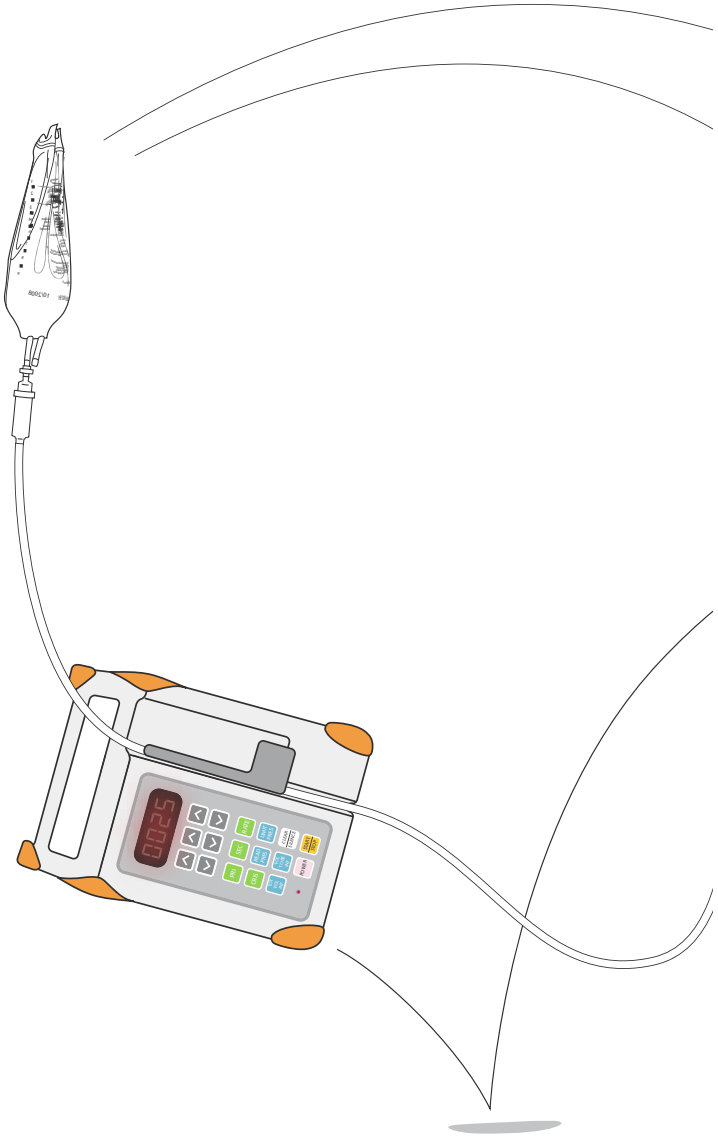
Issue

- Devices are not designed for the rough treatment they receive in hospitals, where they are often dropped.



Recommendation

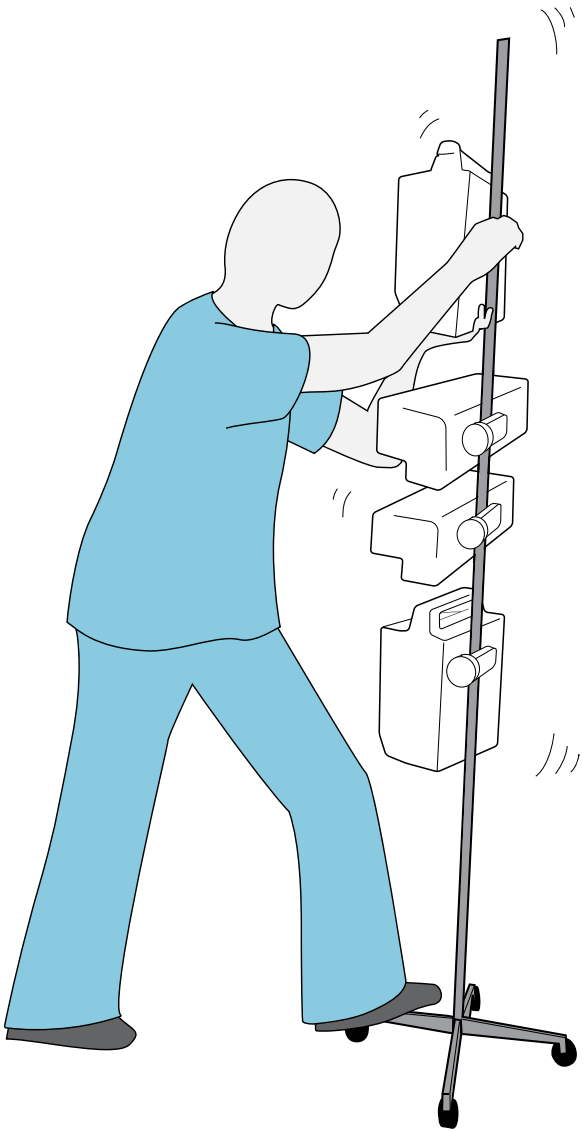
- Manufacturers should consider ways of alerting the user if the device has previously been dropped. The device should clearly specify that it should not be used and must undergo a service after being dropped. Products should be tested for durability, as specified in BS 60601-1:1990, paragraph 21.6.[13] The start-up programme should also check that infusion devices are safe to be used.



1.3a Device stand ergonomics

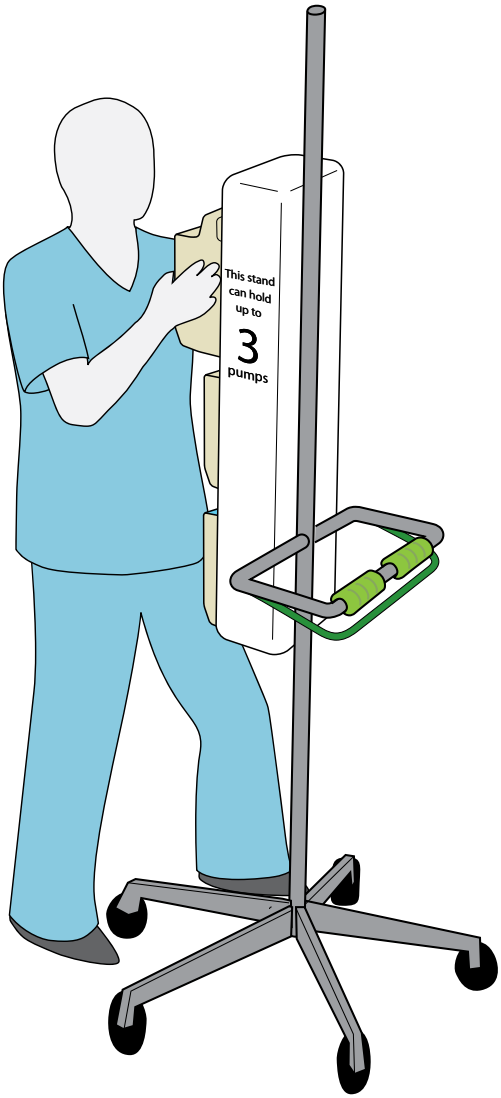
Issues

- Gravity infusion stands are not designed to hold devices and can be unsteady and inclined to topple over.
- Consideration is not given to the manoeuvrability of the stands and movement is very awkward for patients.
- Base units can make stands heavy and cumbersome.
- Stands can be hard to clean.
- Stands can be hard to control during device attachment due to the lack of a braking mechanism.
- Some stand poles are too large to accept all types of infusion devices.
- Attaching devices to stands can be very cumbersome, particularly if there is more than one device already loaded onto the stands. Pole clamps may also be too small to fit around the stand.



Recommendations

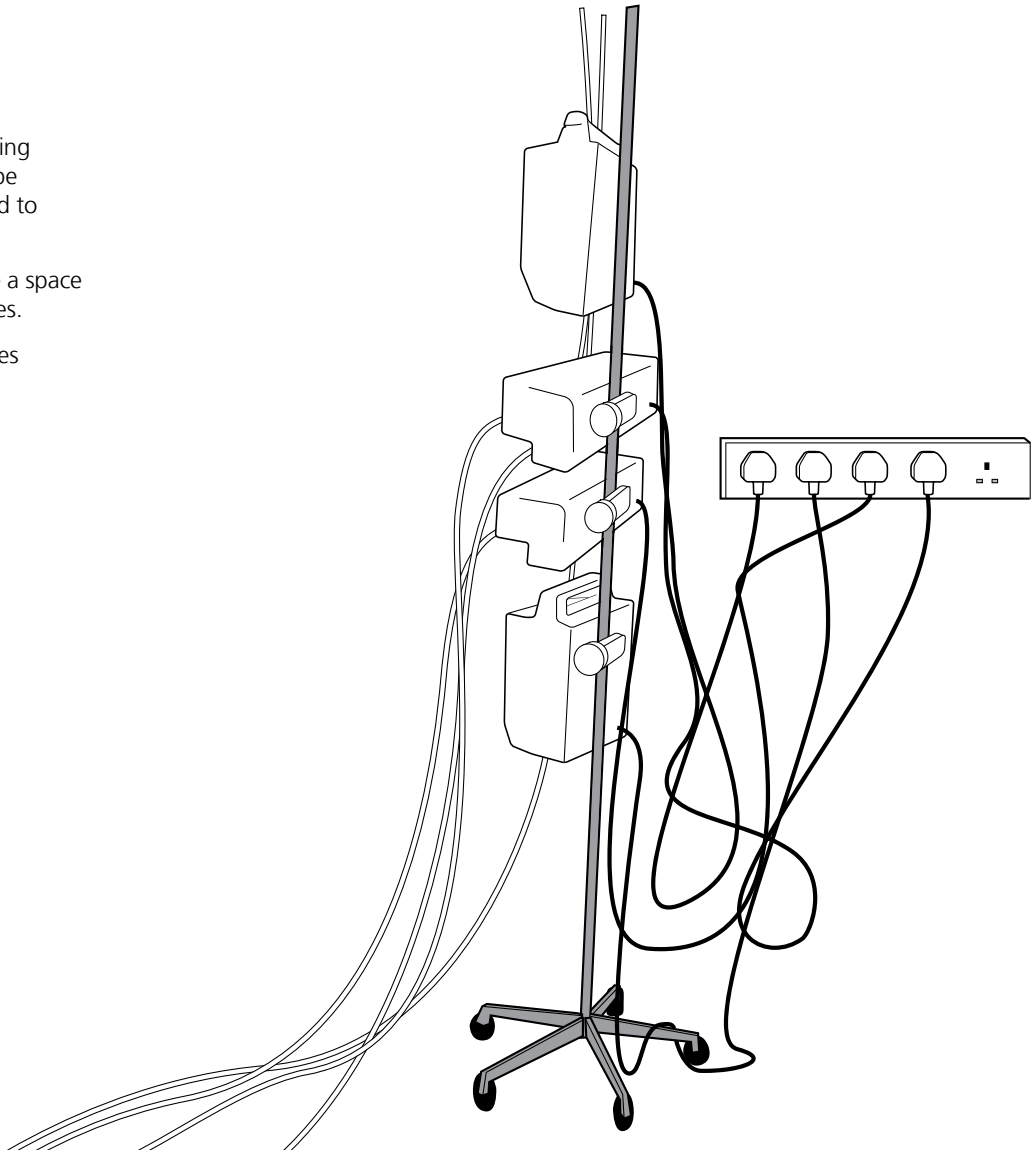
- Gravity infusion stands should not be used to mount infusion devices; equipment stands should be used instead. These should be designed to cater for the additional weight that devices add to the stand. They should also specify how many devices can safely be mounted. Refer to the British Standards for guidelines on stability.[14]
- Equipment stands should have handles to aid patient movement. Larger wheels can also help navigate over uneven floor surfaces.
- Consideration should be given to the manoeuvrability of equipment stands, particularly with regard to the needs of mobile patients.
- Equipment stands should be designed taking into consideration the need for cleaning.
- Manufacturers should consider ways of aiding the device attachment process. Docking stations may be a suitable option, in addition to a parking brake.
- Device manufacturers typically cater for pole diameters of 15-40mm. Hence equipment stand poles should not be any larger than 40mm.



1.3b Equipment stand electrics

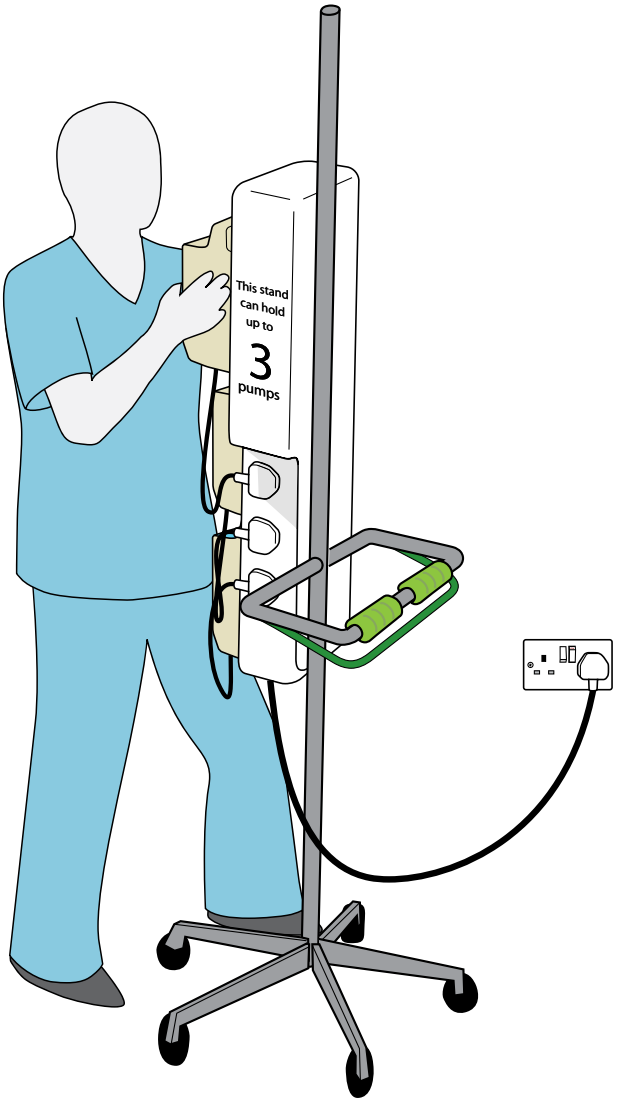
Issues

- With equipment stands holding multiple devices, there may be many power cables that need to be attached to wall sockets.
- Power cables can complicate a space that also contains patient lines.
- Poorly organised power cables can cause a ‘trip hazard’.



Recommendation

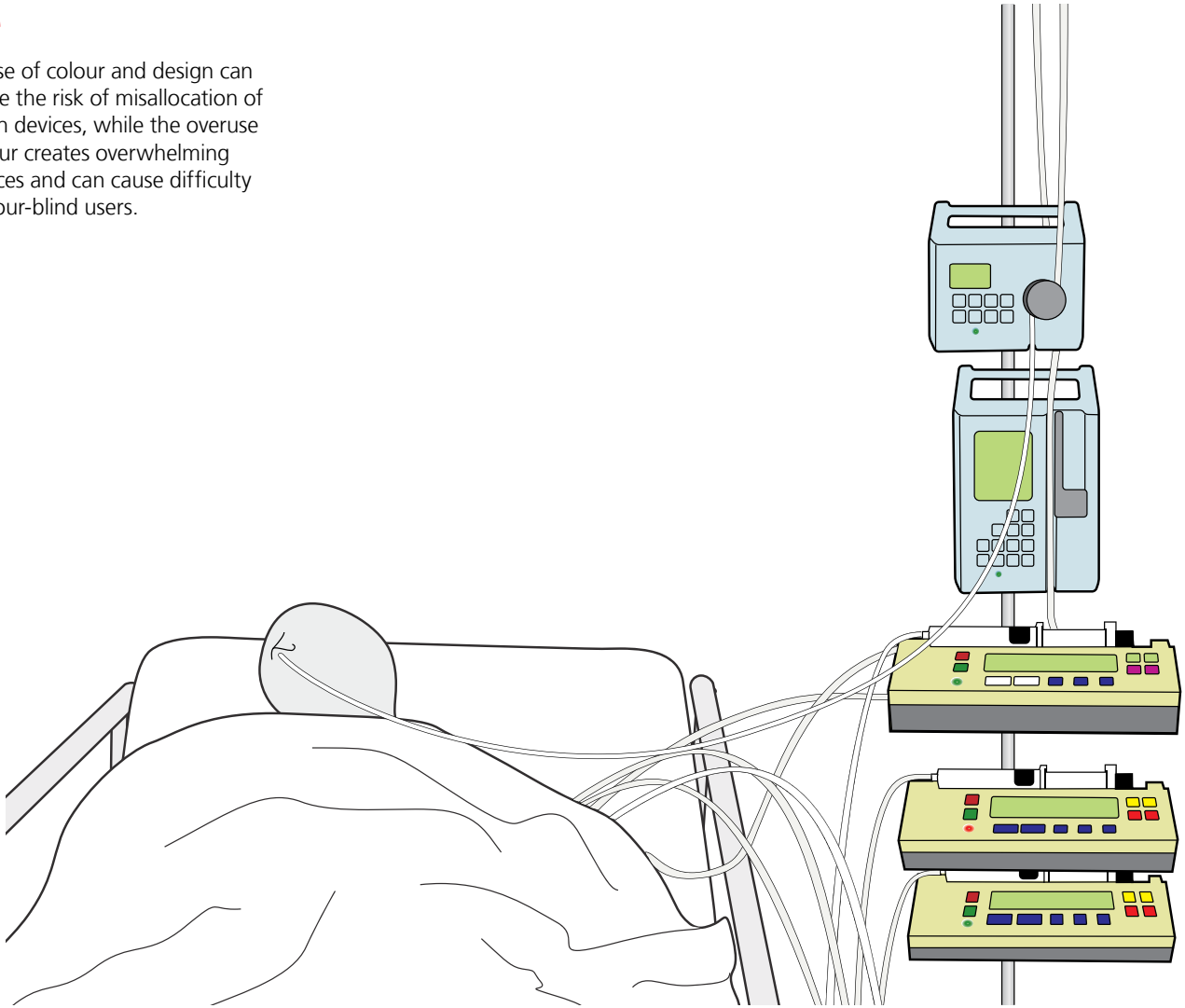
- Consider the incorporation of power sockets to facilitate battery management. Power sockets should be protected from fluid ingress in that they should not point upwards, and should be provided with isolation transformers.



1.4 Use of colour and labelling of devices

Issue

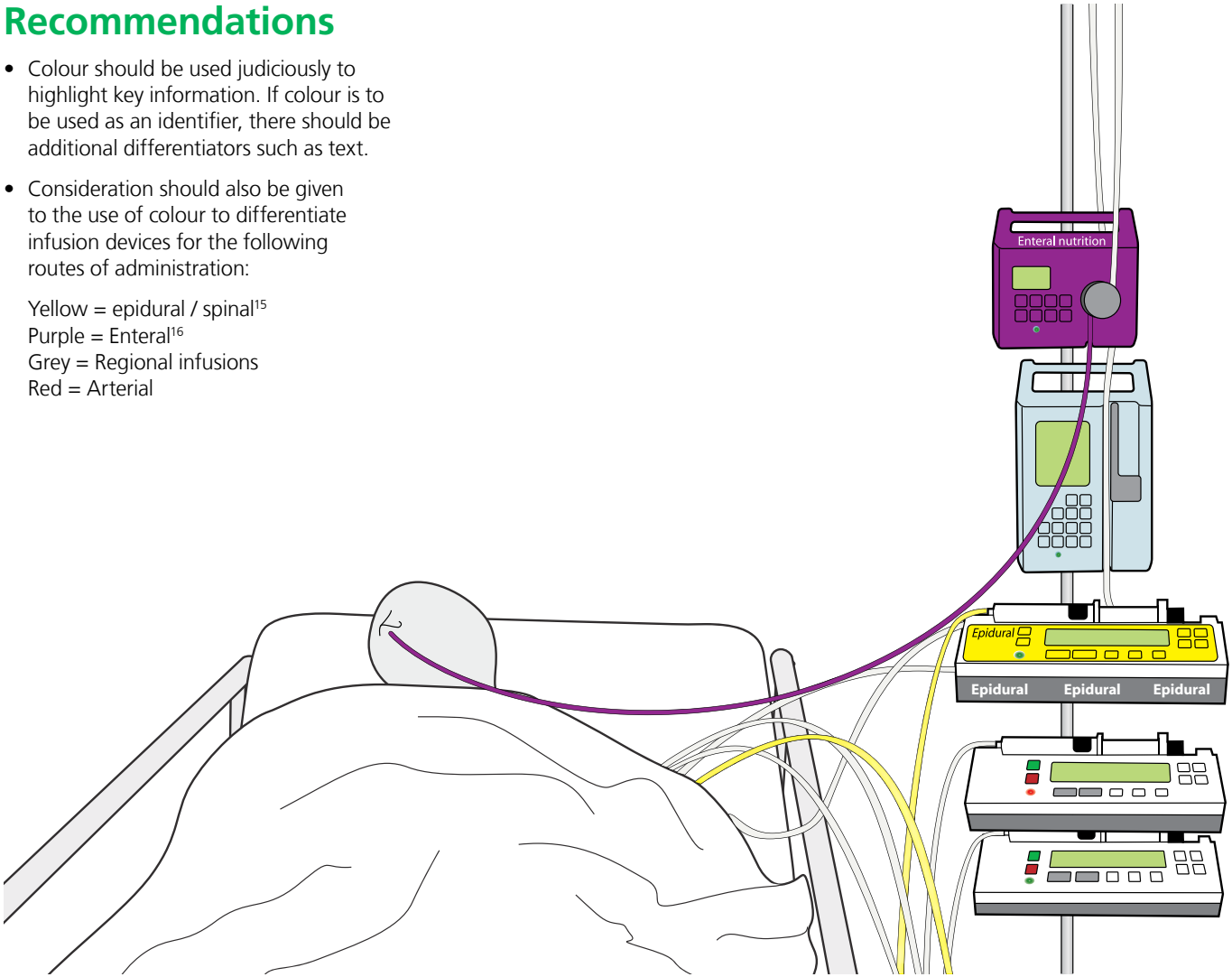
- Poor use of colour and design can increase the risk of misallocation of infusion devices, while the overuse of colour creates overwhelming interfaces and can cause difficulty for colour-blind users.



Recommendations

- Colour should be used judiciously to highlight key information. If colour is to be used as an identifier, there should be additional differentiators such as text.
- Consideration should also be given to the use of colour to differentiate infusion devices for the following routes of administration:

  Yellow = epidural / spinal[15]
  Purple = Enteral[16]
  Grey = Regional infusions
  Red = Arterial

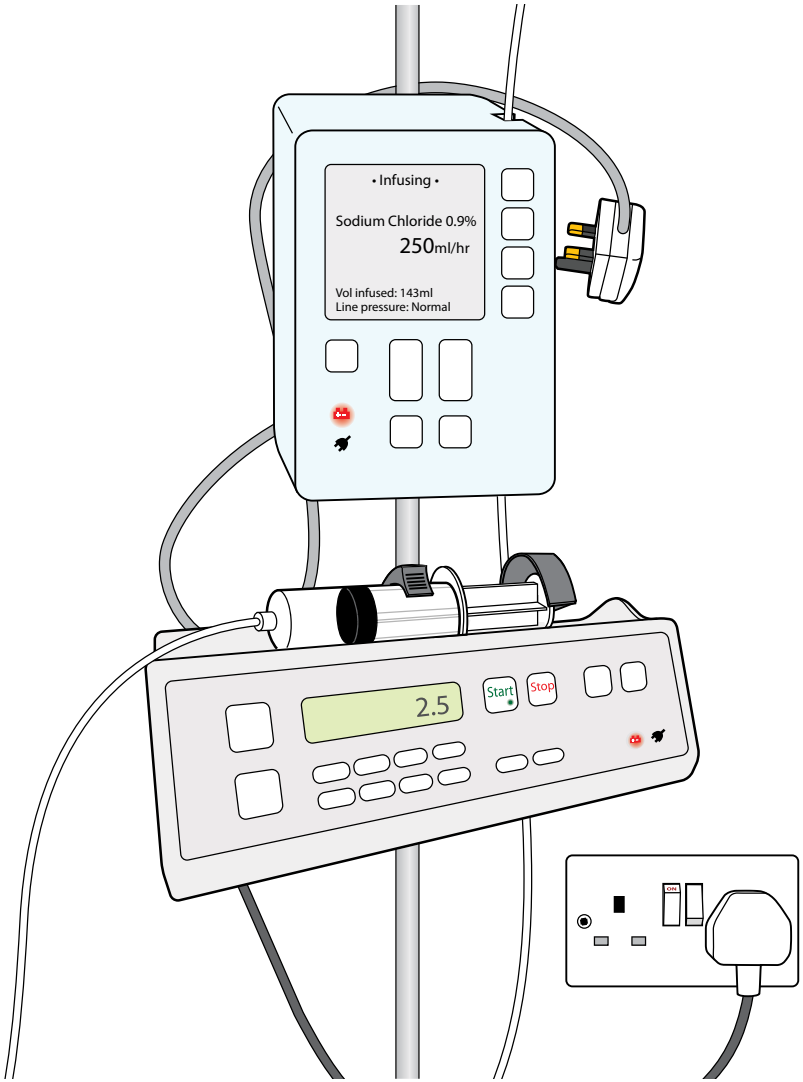


1.5 Power

Clinical users and patients are not always aware that non-ambulatory infusion devices used in hospital wards are intended to be used when powered by mains electricity. The use of battery power is only intended for short periods of time to enable patient transfer or as backup in short power failures.

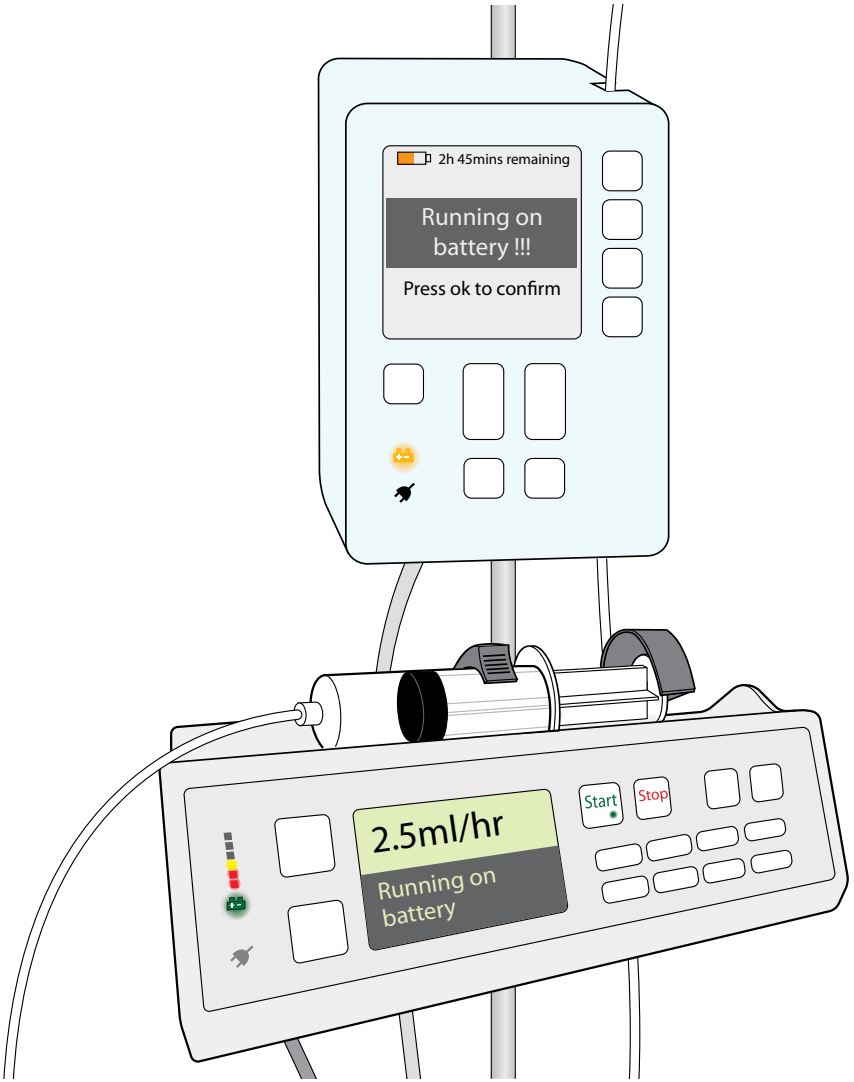
Issues

- It can be unclear whether a device is plugged into the mains supply.
- The level of battery charge is often unclear. This may lead to devices cutting out mid-transfer, or when the patient has taken the device from the ward environment for other reasons such as smoking.
- Power cords may be inadvertently pulled out when the device is in use.



Recommendations

- There should be a clear indication when the device is not plugged into the mains supply. Depending upon the application of the device, for example in intensive care wards, it should require the user to confirm this state. The battery indicator light should clearly indicate that the device is running on the battery power.
- Devices should give an indication of battery life. This should be expressed in hours and quarter hours.
- Consider how to prevent power cords being pulled out, e.g. through the use of a cable anchor or hard wiring power cords. Take care to provide for the needs of the patient as well as the user.



1.6 Device orientation

Issues

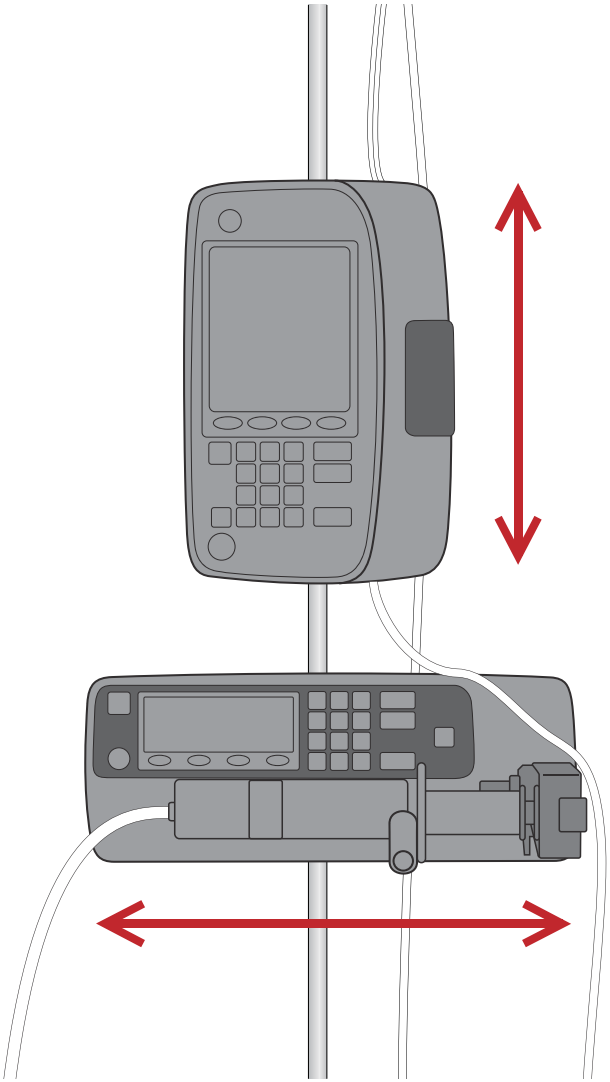
There are various advantages and disadvantages associated with each of the orientations:

Horizontal

- Horizontally-oriented devices are very efficient in the use of the stand and enable the attachment of more devices. However, there is generally quite limited room for the display screen and controls.
- Horizontal line loading systems can cause confusion between whether they should be loaded with the fluid flowing right to left, or left to right.

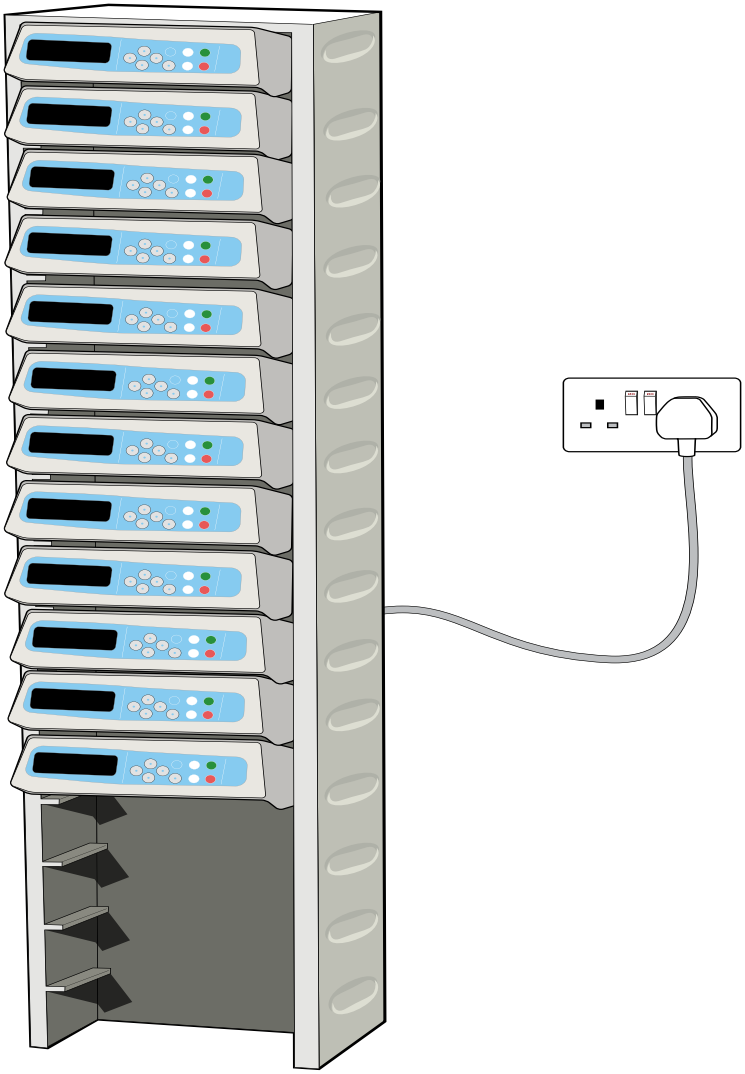
Vertical

- Vertically-oriented devices tend to be much larger and consequently have more space available to accommodate a bigger screen and clearer controls. However, their extra size may make them cumbersome to manoeuvre and allow less devices to be attached to one stand.
- Devices with vertical line loading systems tend to be orientated vertically, and can be more intuitive to use, as it is clear in which direction to load the administration set. However, if a vertical line loading system is to be used on volumetric devices, the device should incorporate a way of preventing fluid ingress caused by leaks or spillage from the bag hanging above.



Recommendation

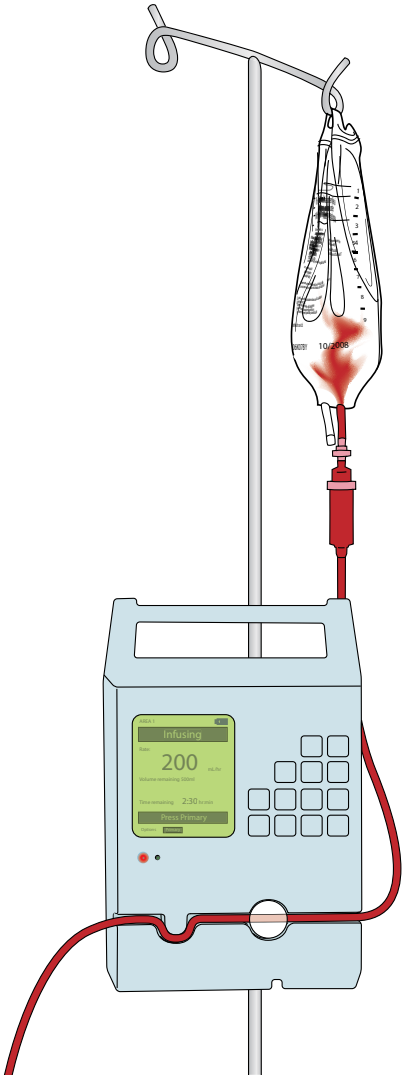
- Manufacturers should consider the most appropriate orientation for their device in the context of its use. For example, devices for intensive care will often be used in greater numbers, and consequently there may be a need to economise on stand space and users may prefer horizontally-orientated devices.



1.7a Loading and priming infusion devices

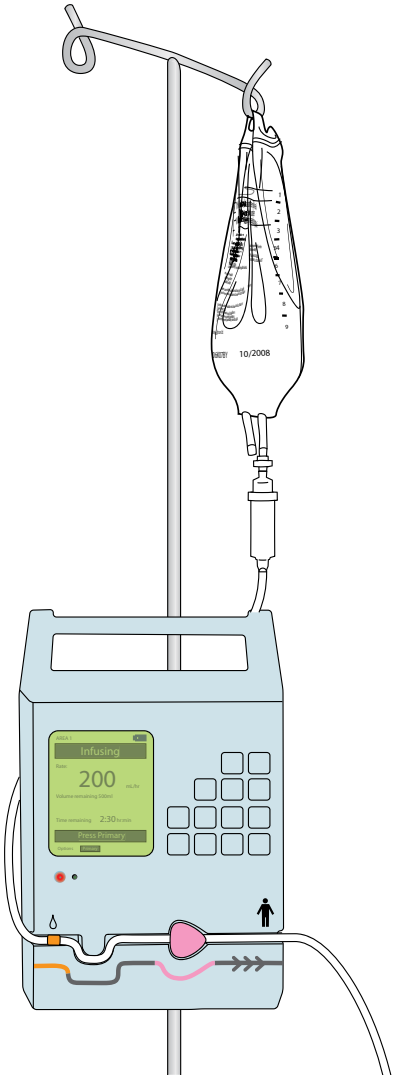
Issues

- It can be unclear if an administration set has been correctly loaded into the device. A misloaded set may withdraw blood from the patient instead of administering medicine.
- Line loading can be an awkward, complex process with very little signposting to aid the user. Horizontal feeds can be particularly confusing, and it can be ambiguous as to which way administration sets should be loaded into the device. The line may go from right to left, or left to right.
- Lines may not be primed before beginning the infusion.
- In-line cassettes can complicate line loading processes.
- Fluid may leak from the bags into the device, causing the device to fail.



Recommendations

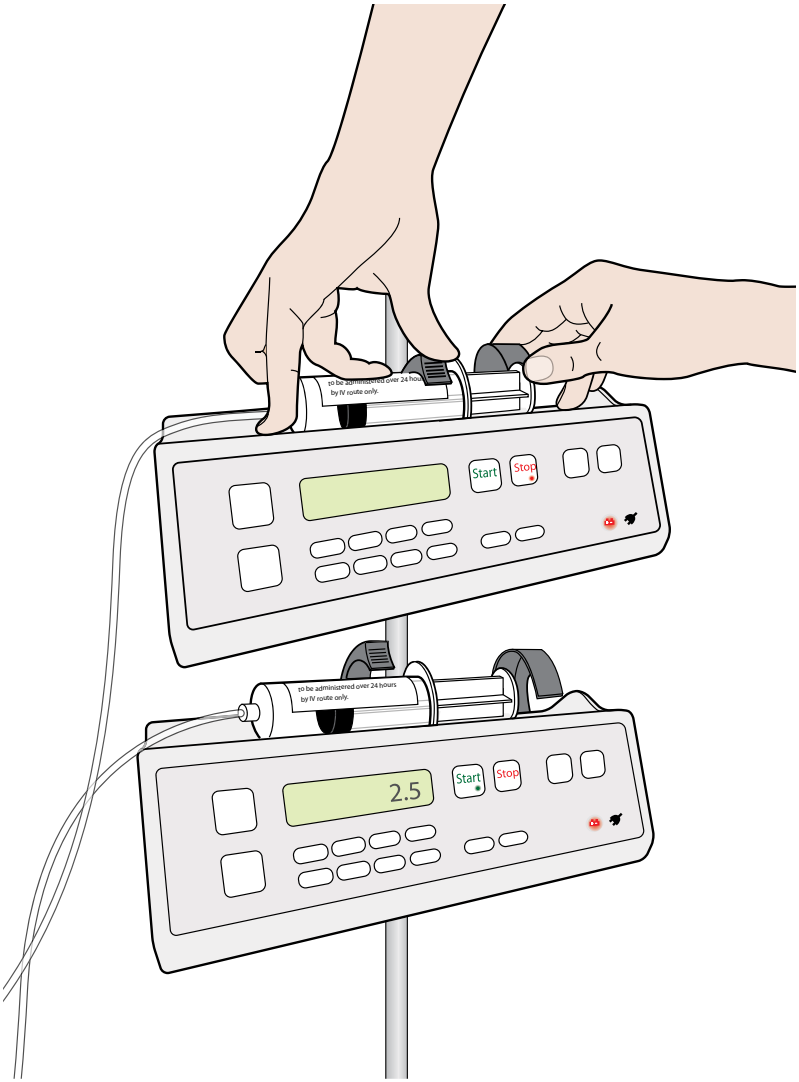
- Loading mechanisms should be designed such that incorrect loading is impossible. It should be immediately apparent when a line has been misloaded, with a corresponding alarm message on screen. The device should not function if it has been loaded incorrectly.
- Clear instructions should be visible to the user for the line loading process. There should always be an indication as to the direction of the fluid flow to prevent confusion.
- Cassettes should be easy to install in the device. Good design should indicate the orientation of the cassette, and aid its installation.
- Devices should prompt the user to prime the line and provide functionality to aid this process.



1.7b Loading and priming syringe devices

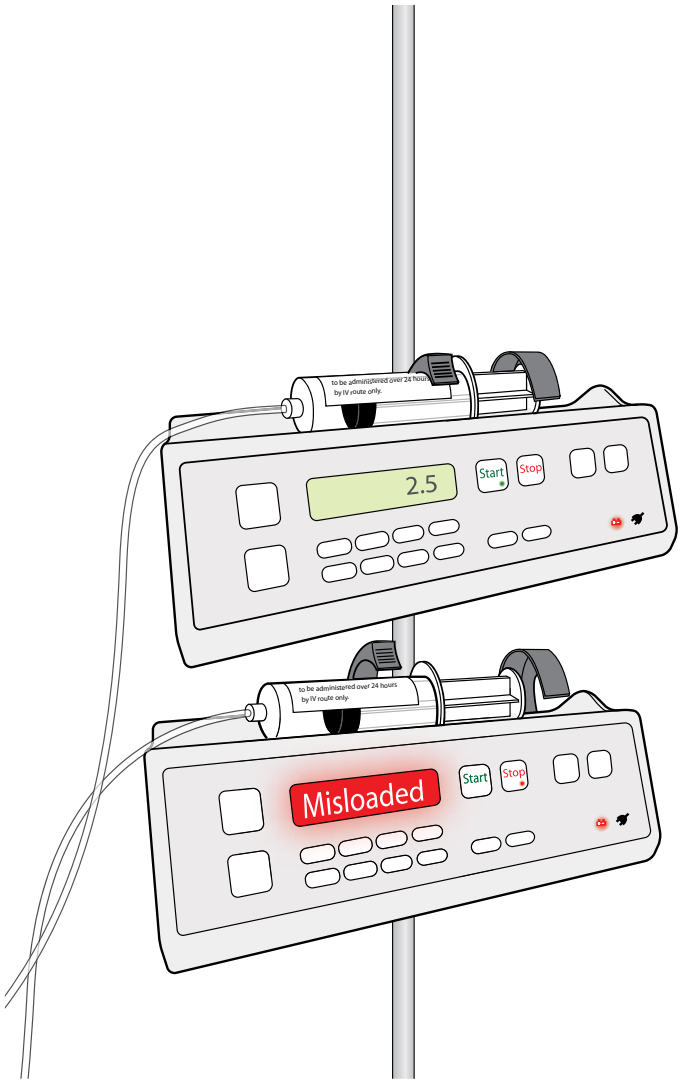
Issues

- Fitting the syringe into the device can be a complex and unwieldy process.
- The syringe and plunger may not be secured into the device, potentially allowing the entire contents of the container to free flow into the patient.
- The syringe driver may not be calibrated for the make and size of syringe used.
- The syringe and giving set may not be adequately purged, with the consequential mechanical backlash delaying treatment.
- The syringe label may not be visible when fitted into the driver.



Recommendations

- The syringe loading process should be simple and able to be performed by users with limited dexterity. Simultaneous actions should be avoided where possible. The device should not function when loaded incorrectly.
- The device should be designed to ensure that the syringe and plunger cannot disengage. It should also have corresponding alarms to alert the user to misloading and potential free flow.
- Auto-sensing should detect the brand and size of syringe being used and should require confirmation from the user. The auto-sensing should be configured by the medical engineering department for organisation approved syringes and sizes.
- The pump should alert the user if an unrecognised and non-calibrated syringe is attempted to be used. Software settings need to be set to ensure specific syringes deliver fluid accurately.
- The device should prompt the user to prime/purge the line when the syringe is in place and not connected to the patient, to reduce any mechanical backlash.
- The syringe label should always be visible to the user when fitted into the driver.



1.8a Device controls – numeric input keypads

Issues

- Infusion devices use different layouts for numerical keypads, causing confusion amongst users.
- The continued used of two alternative numeric keypad layouts can lead to miskeying errors.
- The keypad layout may be rearranged, placing the '0' and '.' in unexpected places.

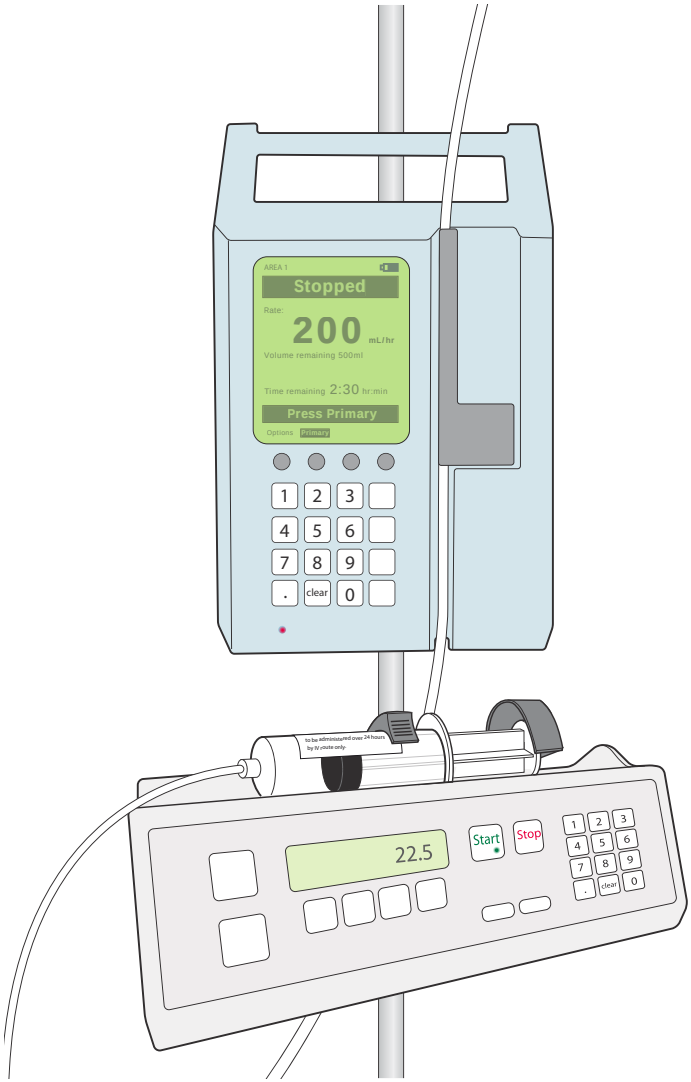
Recommendations

- The extensive use of mobile phones, and its frequent additional function as a calculator, supports a recommendation that staff are more familiar with the telephone layout. This layout, where the number ‘1’ is in the top left corner, should be used on all devices.
- The numerical layout should not be altered. The ‘0’ and ‘.’ should always be positioned below the rest of the numbers and not adjacent to each other.

1.8b Device controls – other numeric input

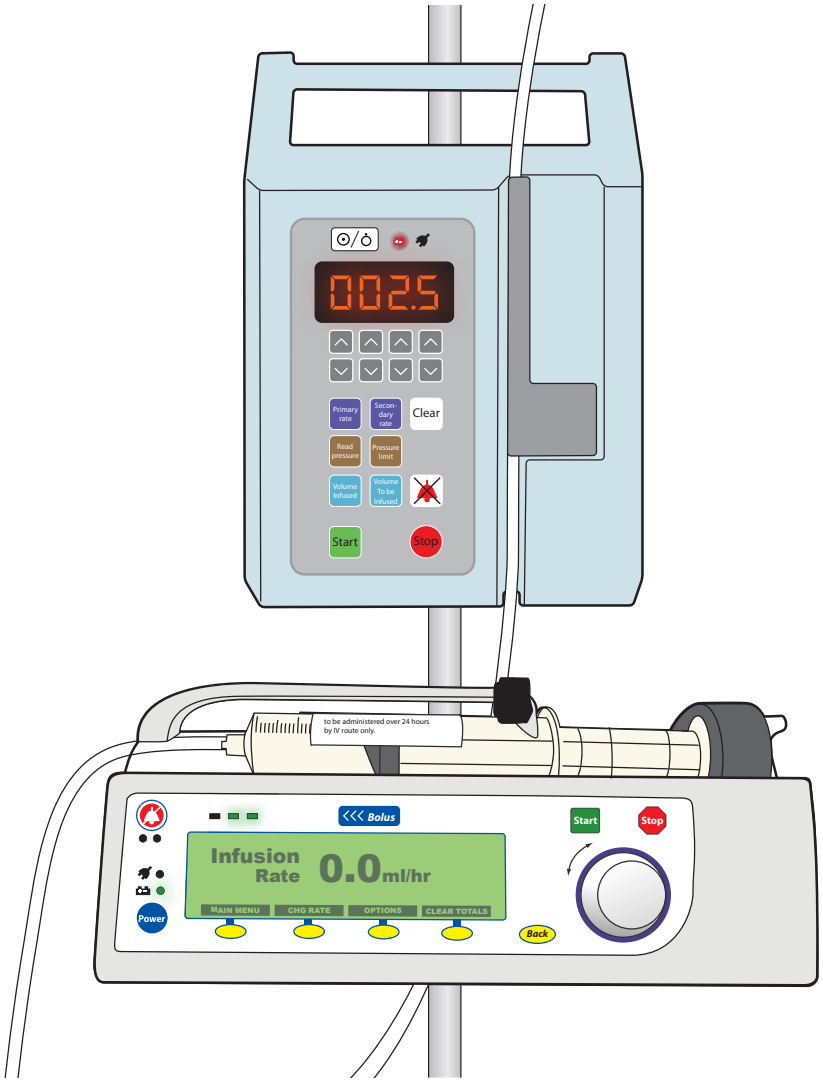
Issues

- Numeric keypads can cause input error due to the user needing to look at the keypad and not the screen whilst entering.
- Push-button keys may sometimes register multiple presses when only one was intended.



Recommendations

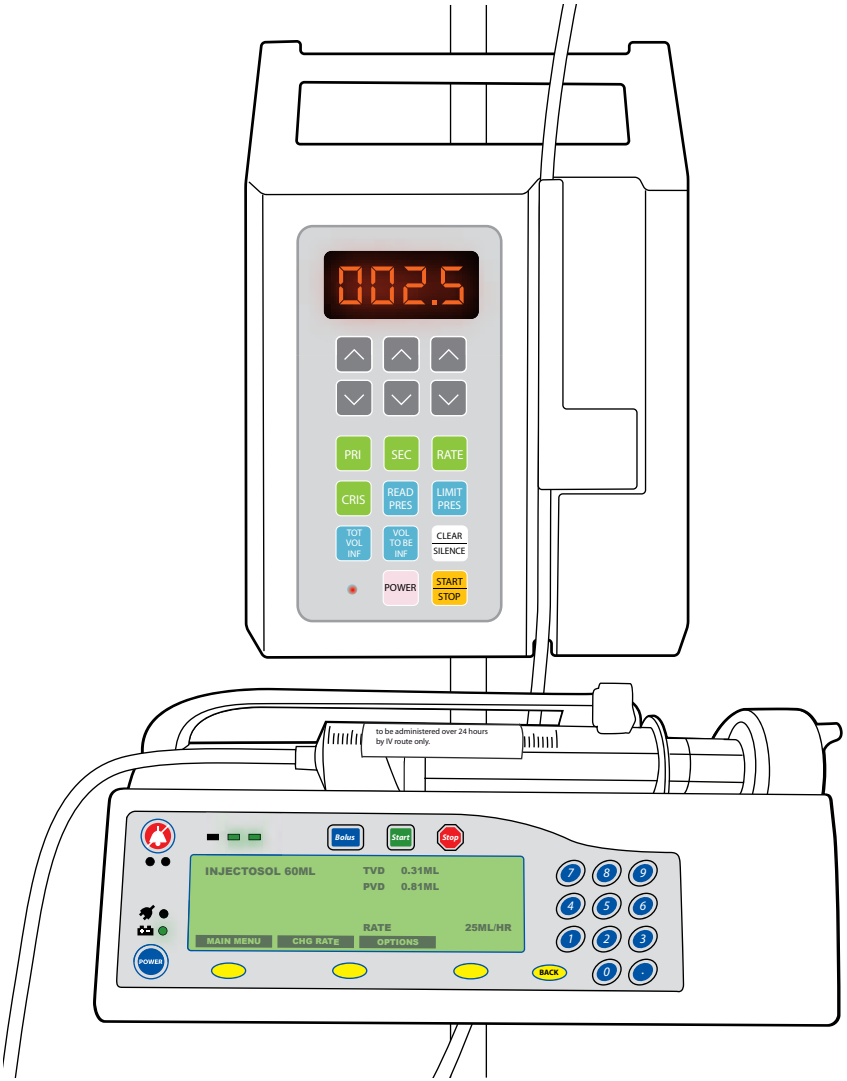
- Consideration should be given to analogue methods of input such as dials and chevron keys. These can be more intuitive with regard to quantity and allow the user to monitor the screen during input.
- Push-button keys should be designed to give positive feedback when pressed and avoid multiple jumps. This will reduce the risk of rate overshoot.



1.8c Device controls – other buttons

Issues

- It can be unclear what function soft keys perform or what figures they correspond to, for example, three soft keys controlling a four figure display. Vertically arranged soft keys can be subject to parallax error, especially when the device is positioned above or below eye level.
- It can be ambiguous which figures arrow keys refer to.
- The start and stop functions may be provided by one button, which may cause ambiguity as to which operation is being invoked.
- Numerous key presses may be required in order to reach a particular desired function.



Recommendations

- It should be clear what action soft key controllers perform with only one soft key per digital display. Consider adding lines from the soft keys to the display to indicate which selection they refer to.
- Controls should be spaced logically and ensure that there is sufficient space between them. Consider grouping buttons of similar functions together.
- Consideration should be given to making 'start' and 'stop' into two distinct buttons. Where the 'start' and 'stop' are one button, a clear message should tell the user what action the device is performing. Key buttons such as the bolus, start, stop and on/off buttons should be positioned away from the main group of buttons.
- Minimise the number of key presses required to perform any function, although for safety reasons certain functions require two distinct actions to initiate.

1.9a Symbols – ISO standards

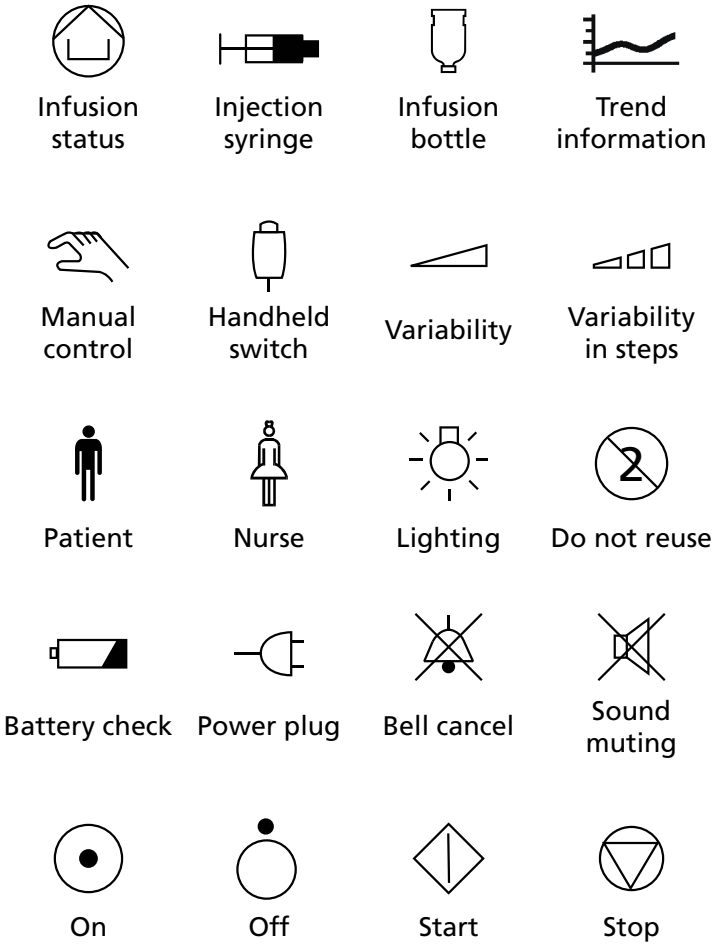
Manufacturers are increasingly replacing text with symbols on their device controls. This enables one product to be marketed to many countries and overcomes many of the different language requirements.

Issue

- The use of symbols introduces new risks as symbols may be poorly understood by users.[17] Some symbols have been included in IEC 60878. However, the meaning of these symbols is not always intuitive or well known by healthcare users.[18]

Recommendations

- It is recommended that manufacturers add text labels to symbols and/or improve understanding of symbols in other ways, until the meaning of the symbols are universally recognised by users.
- Symbol recognition and understanding of function should be incorporated into training and competency assessment materials.



1.9b Symbols – manufacturer variations

Issue

- Manufacturers devise their own symbols for device controls in addition to using ISO standards symbols.[19] Non-standard symbols may be misunderstood by users.

Recommendations

- It is recommended that wherever possible ISO standard symbols with text be used rather than using the manufacturers' own symbols. Where the required symbol is not available as a standard, the manufacturer should seek to influence the ISO standard to include a new symbol.
- Symbols need to be tested with users in context. There is an ISO standard for developing and testing symbols with users.[19]
- It is recommended that manufacturers add text labels to symbols until the meaning of the symbols are universally recognised by users.
- Symbol recognition and understanding of function should be incorporated into training and competency assessment materials.

The on/off button should be the only button with 2 functions. In line with MHRA requirements, turning off the pump should be a 2 step process requiring confirmation from the user.

Use green as an additional indicator for the start button

Use red as an additional indicator for the stop button

Use 3 arrows to indicate the bolus function and avoid confusion with rewind / fast forward icons.

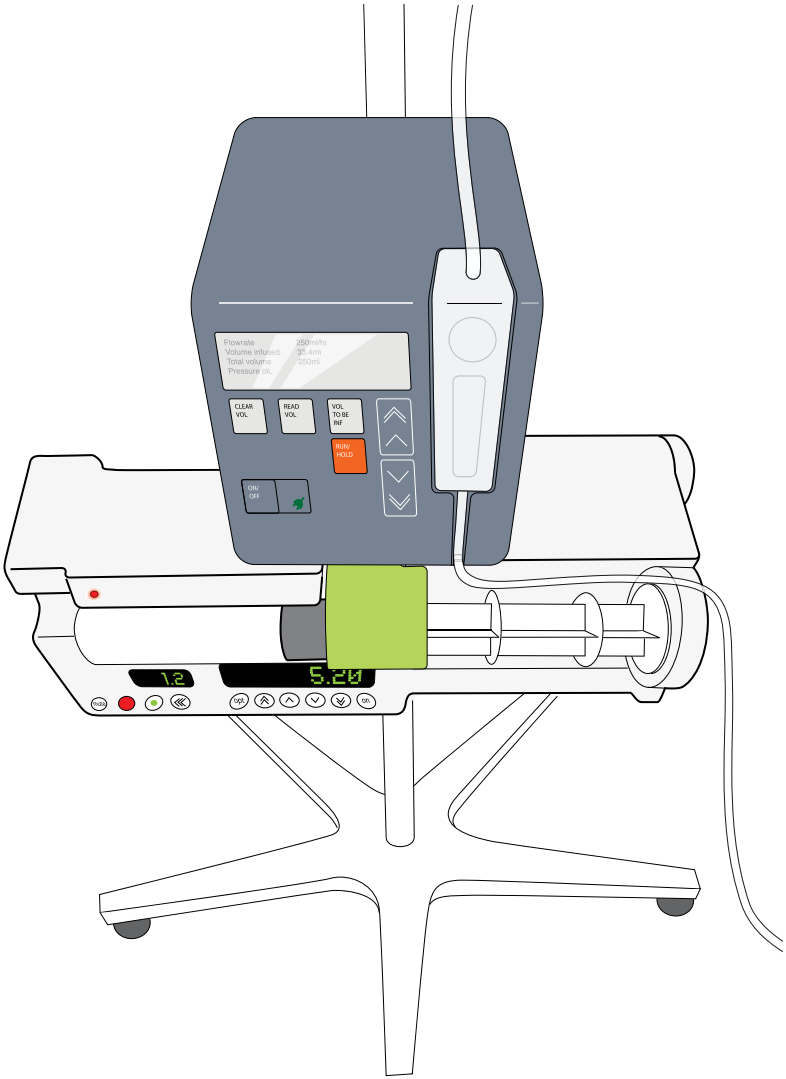
Keep icons simple and minimalist. Remove any unnecessary graphics where possible.

Where abstract icons are used, use labels to help identify the button.

1.10 Display screen

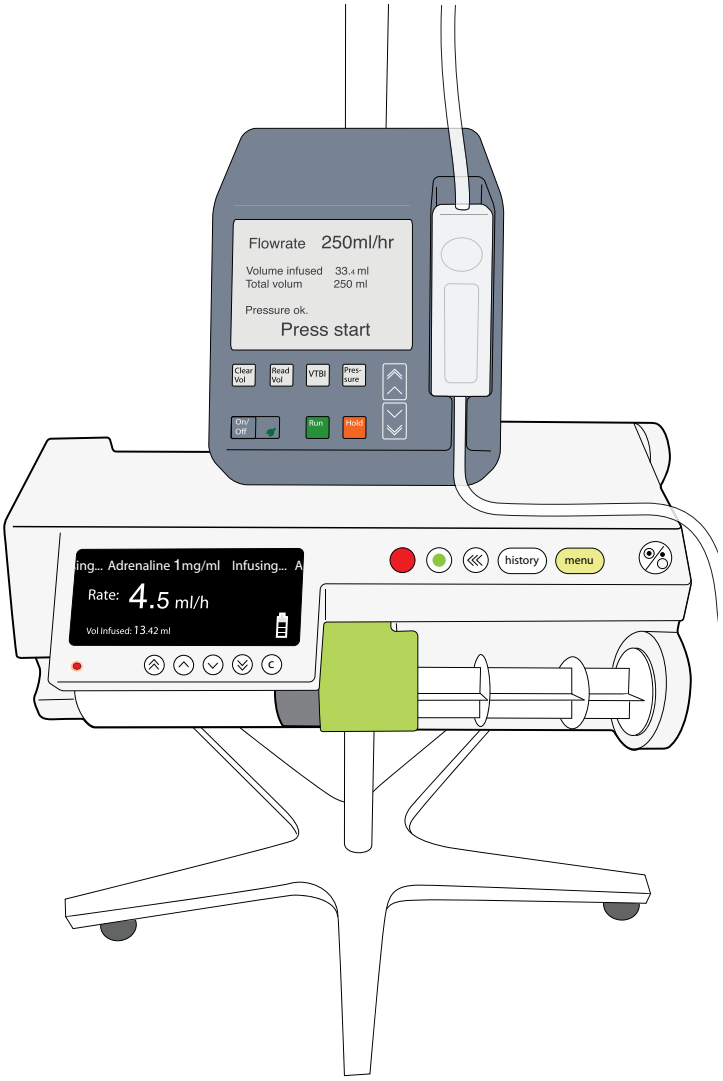
Issues

- Screens are too small to be able to display the key information properly.
- Screens cannot be seen when interacting with devices due to the screen angle.
- Light reflections can impede legibility of information.
- Screens cannot be read in dark lighting conditions.



Recommendations

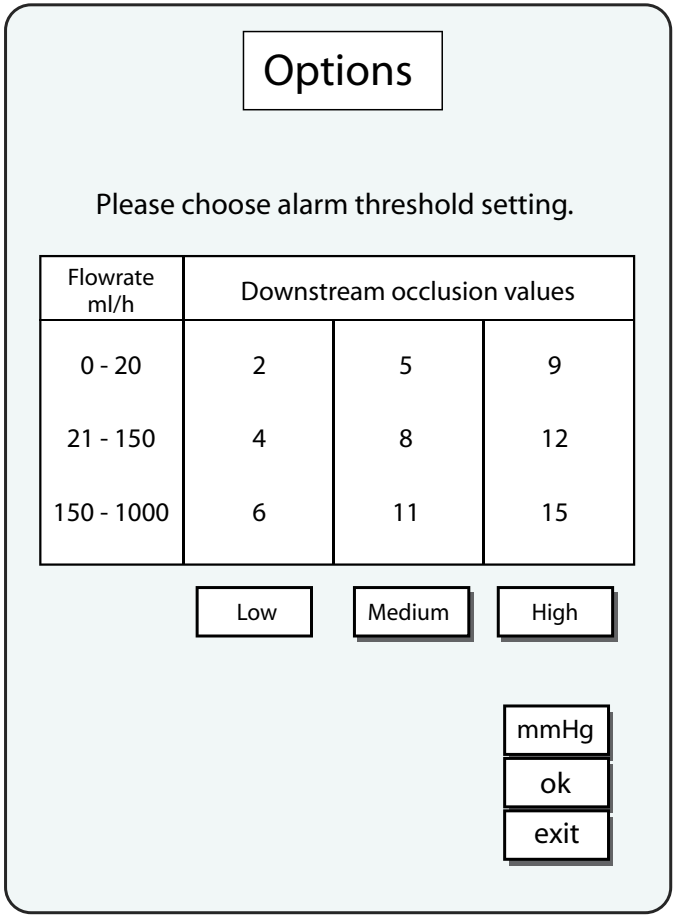
- Screens should be large enough to display the key information without causing user confusion.
- Consideration should be given to the visibility of screens when devices are stacked. Tilt the screen towards the user where possible.
- Use non-reflective finishes to reduce reflections.
- Screens should have variable backlighting settings to maximise usability and patient comfort.
- Display screens should have high contrast between background and text. Where monochrome displays are used, manufacturers should consider inverting the text and background colours. These can be more visible than other types of screens in all lighting conditions.



1.11 Touch screens

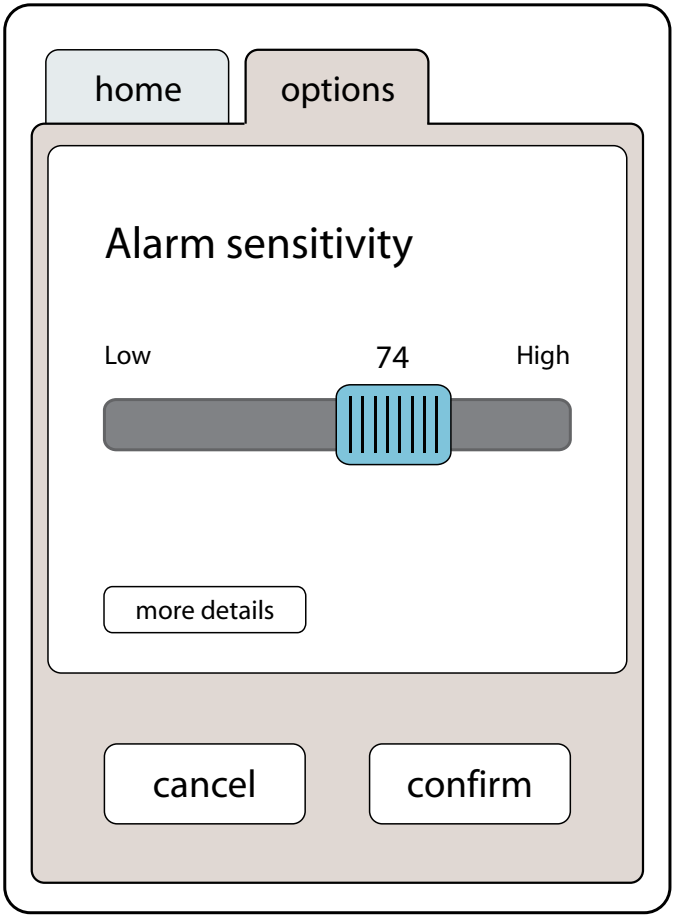
Issues

- Touch screens are usually operated with a finger or stylus, however, touch screen controls may be too small to be easily selected and operated using a finger.
- Keying in many numbers or letters by finger pointing may be time-consuming and error-prone if the sensitivity of the screen is not set correctly.
- Buttons are touched to provide information, provide options and initiate action. Unintended action may be initiated whilst reviewing information and selection options.



Recommendations

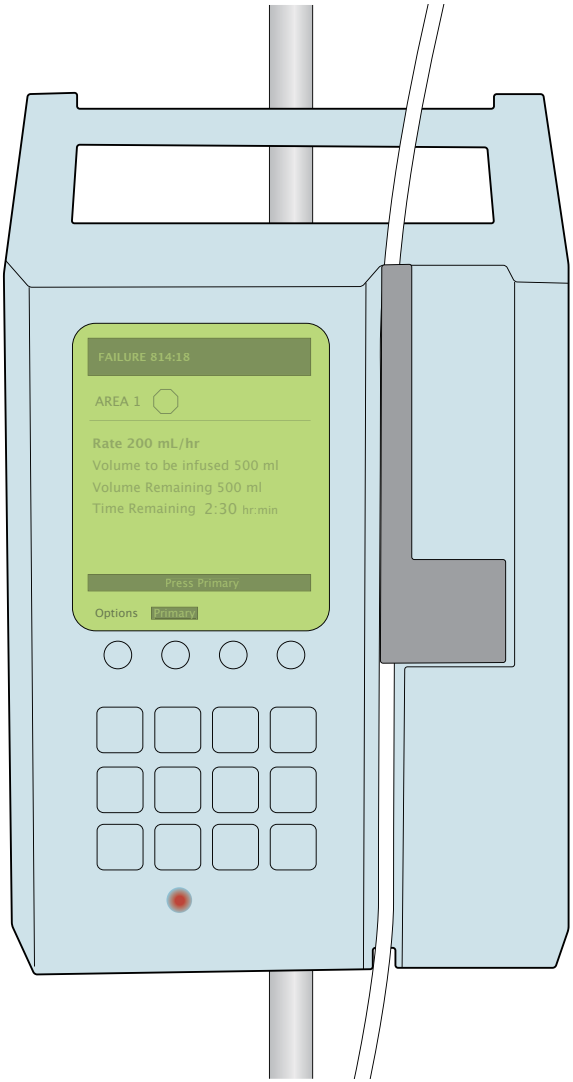
- Points of interaction should be made intuitive and be large enough to be pushed by a finger. Buttons should not be less than 12mm wide.[20,21] However, the minimum size of vital buttons should be at least 2cm wide with 1mm spacing in between.
- The software should be error-tolerant and allow the user to backtrack easily.
- Creating invisible active areas around buttons may help to ensure the correct button is pressed. Manufacturers should also consider using finger 'lift-off' button activation rather than 'land-on' activation.
- Use list selection options where possible to avoid many button presses and user fatigue.
- Create tactile feedback for the user. Non-audible methods are preferred.
- Group buttons of similar function together to streamline hand movement.
- Action buttons should be positioned at the bottom of the screen so that consequences are not obscured by the hand or arm.



1.12a Alarms

Issues

- It can be unclear how serious or important an alarm is, and also what effect this has on the device functioning.
- Frequent alarms can cause irritation to the user and patient, and may result in alarms being ignored or cancelled.
- It can be hard to know why a device is alarming or how to remedy it. Abbreviated warning messages or failure codes can lead to confusion about how to rectify the situation.
- It can be hard to identify which piece of equipment is alarming, particularly on intensive care wards, where equipment may be stacked up.
- It is possible to silence the alarm by pressing keys other than the alarm silence key.



Recommendations

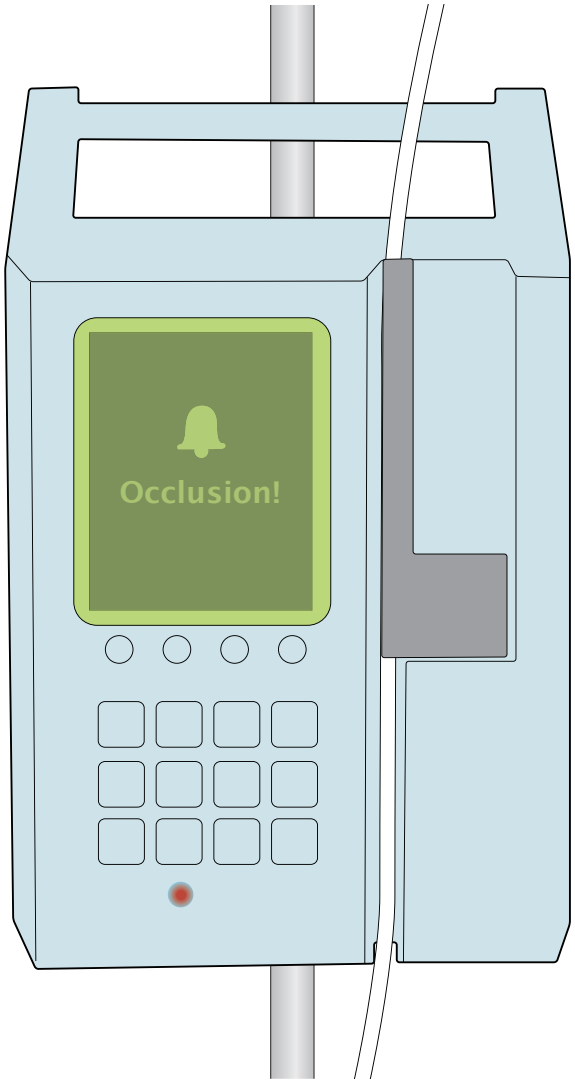
- There should be no fluid flow when the device is alarming, or a minimal flow if a 'KVO' (Keep Vein Open) setting is operating. Differentiate between an alert and an alarm, through the use of different colours and audio rhythms.[22]
- Alarms should occur when:

  - air is present in the line;
  - the line is occluded;
  - the infusion is ending;
  - the administration set has not loaded properly;
  - the syringe is dislodged or disengaged from the device;
  - the battery is flat.

- Alerts should occur when:

  - the main supply is not plugged in;
  - the device is on and the infusion is not running;
  - the infusion programme is being changed whilst the infusion is running;
  - the battery is low (at least 30 minutes before power runs out).

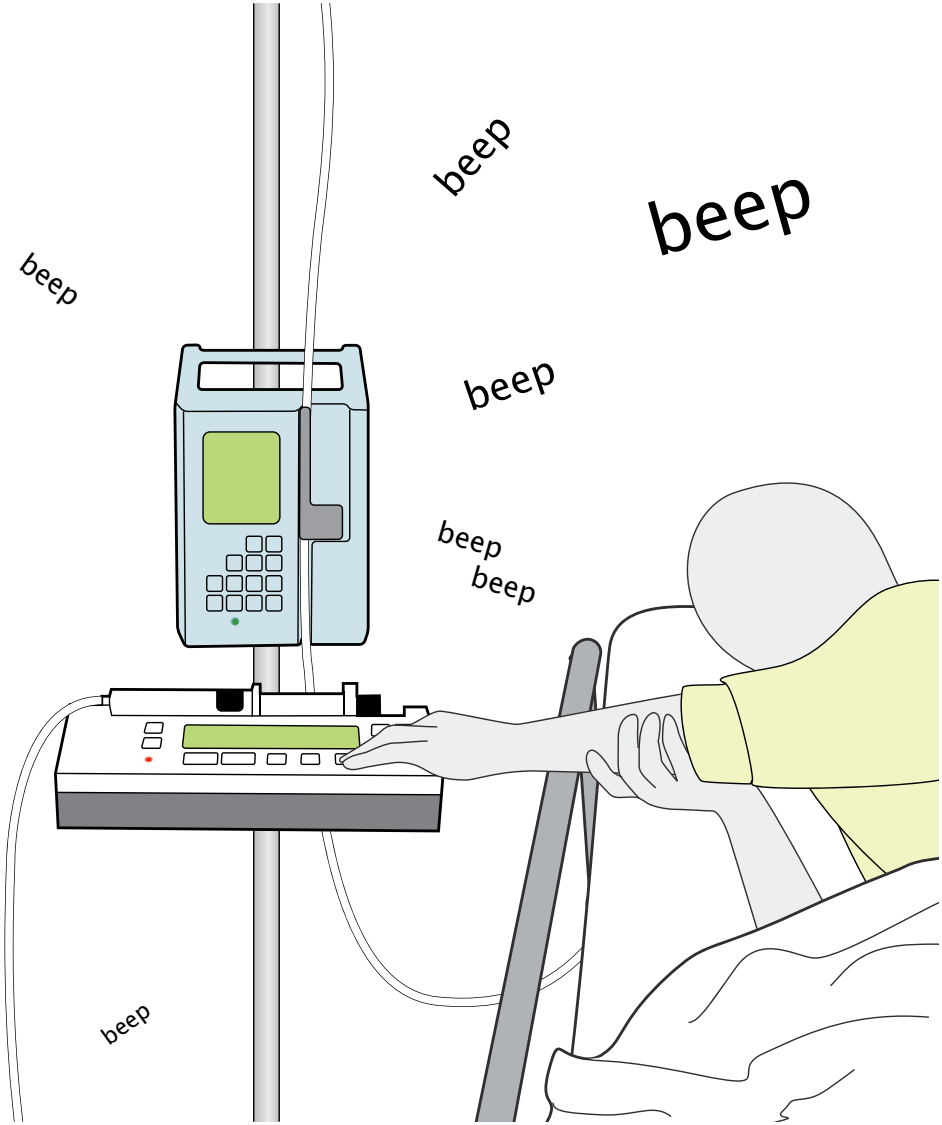
- Alarms should be clearly visible as well as audible, with alarm messages presented in clear, simple English (or the language of the country).
- Abbreviations should not be used.
- Users should only be able to silence the alarm by pressing the alarm silence key and/or rectifying the cause of the alarm. The alarm silence button should silence the alarm for a period of time, for example for up to two minutes, if the alarm condition is not rectified.



1.12b Alarm signalling

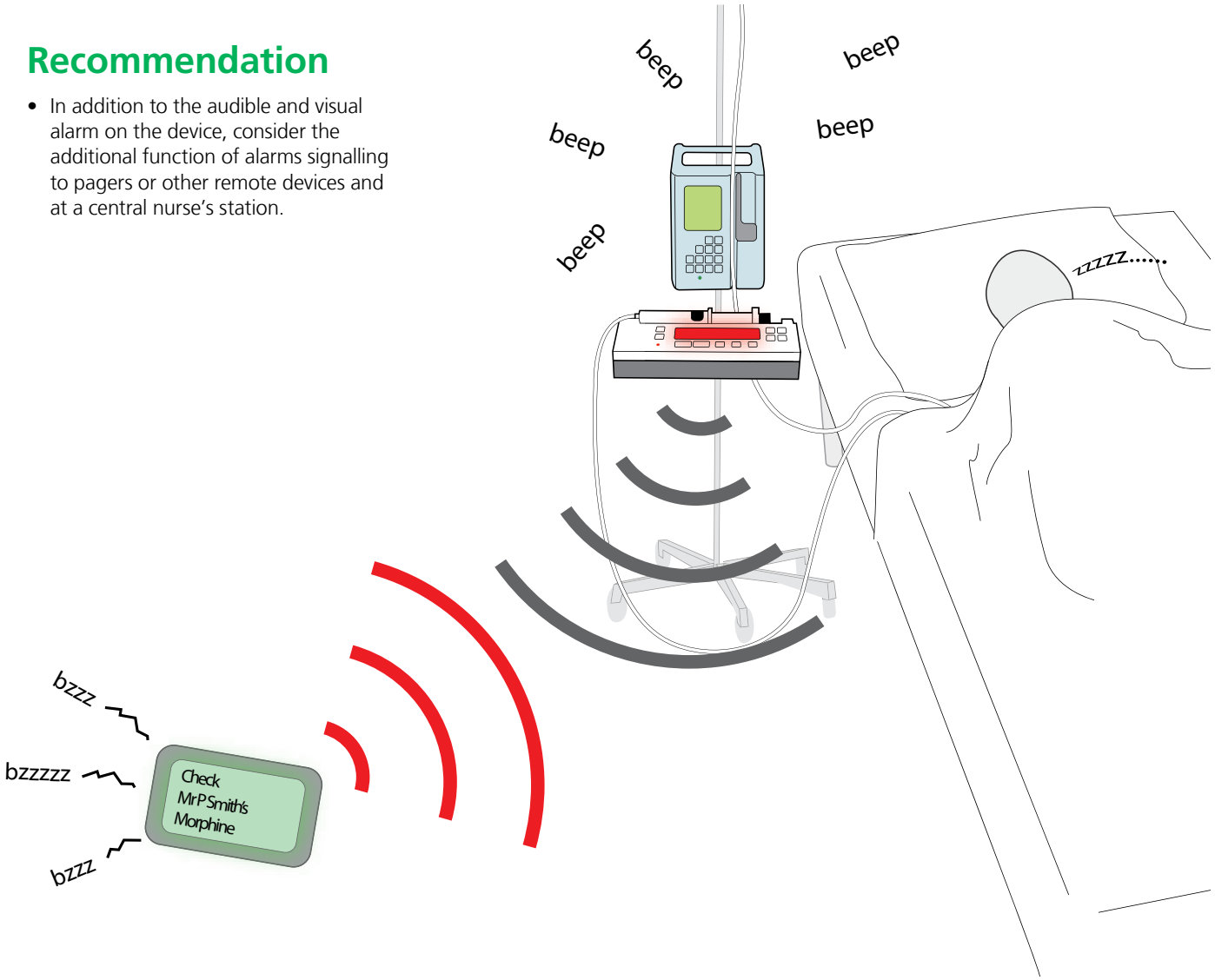
Issue

- Devices alarming while attached to patients in isolated rooms may not be noticed by nursing staff.



Recommendation

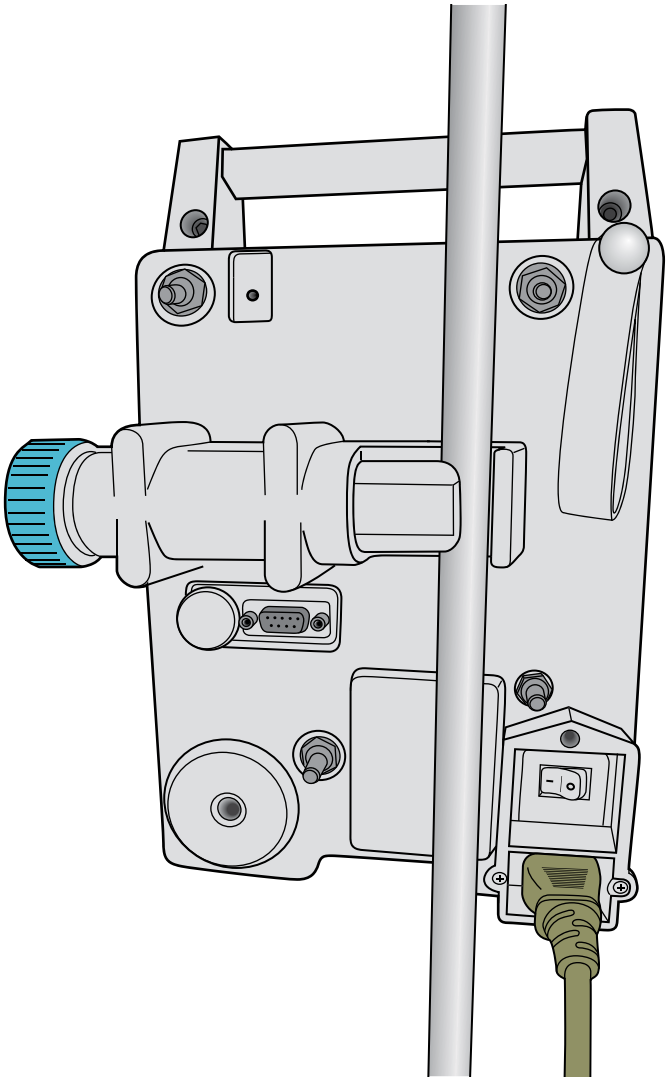
- In addition to the audible and visual alarm on the device, consider the additional function of alarms signalling to pagers or other remote devices and at a central nurse's station.



1.13 Cleaning

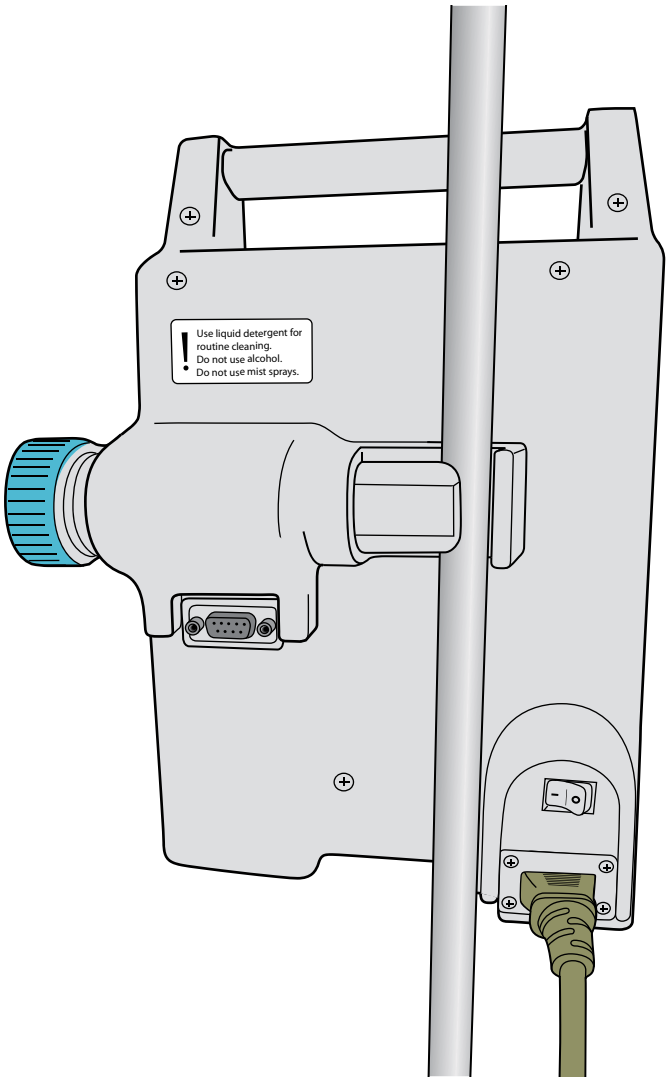
Issues

- Devices are cleaned on a daily basis, but poorly designed devices take longer to clean, and may provide nooks and crannies where dirt and dust can accumulate.
- It can be unclear how to clean a device effectively, with poor or incomplete cleaning instructions provided in the user manual.
- Users may not be aware of manufacturers' recommendations on how to safely clean device surfaces and use alcohol impregnated wipes and mist sprays, which degrade plastic and penetrate into poorly sealed devices.
- Surface markings may become faded or damaged due to the cleaning agents used.
- Sensors become dirty but poor device design prevents them from being cleaned.
- Devices may be cleaned whilst in operation, and controls accidentally altered.



Recommendations

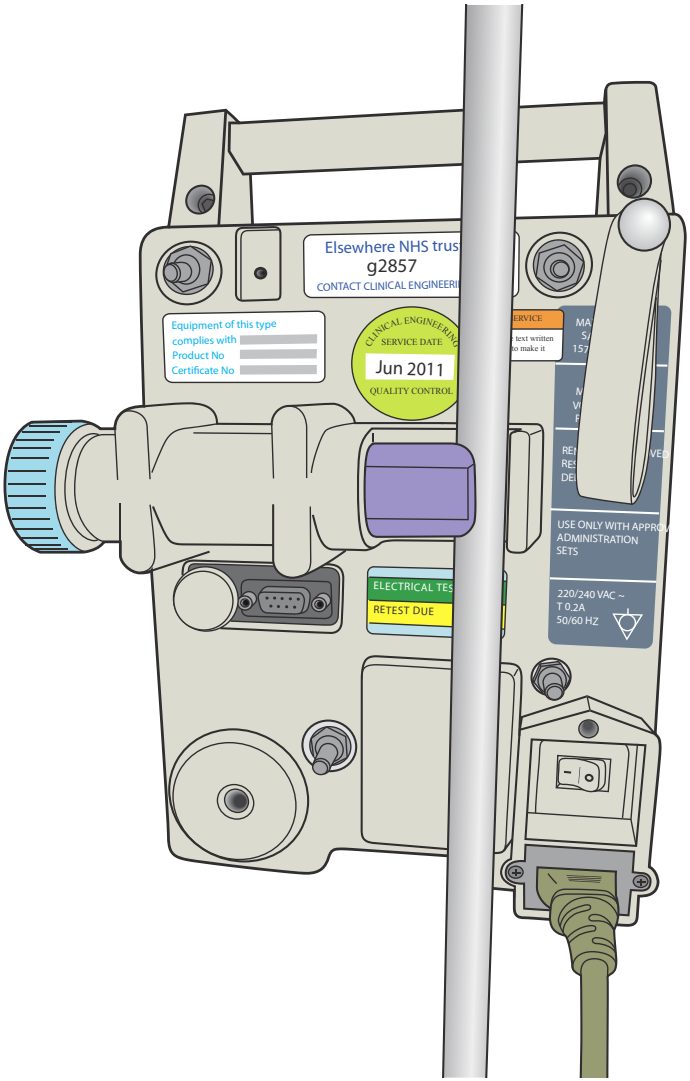
- As far as possible, devices should be designed to have easily cleaned surfaces, with filled corners and no crevices. IT connections should be recessed into the device. Where grooves are necessary (for example with heat sinks), make these large enough to be able to clean easily.
- Manufacturers should provide comprehensive cleaning instructions in their user manual, on devices, in software and online to help prevent confusion and promote infection control.
- Device surfaces should be resistant to fluid ingress and be fitted with watertight seals. Moulded shrouds or umbrellas can reduce the risk of fluid ingress by directing drips and leaks away from inlets.
- Manufacturers should clearly specify what cleaning agents should be used on their products. Surfaces should be able to withstand cleaning with alcohol, hydrogen peroxide, hypochloride and other standard cleaning agents.
- Sensors should be designed to enable access for cleaning purposes.
- Incorporating keypad locks into devices can help prevent accidental changing of settings whilst cleaning.



1.14 Maintenance

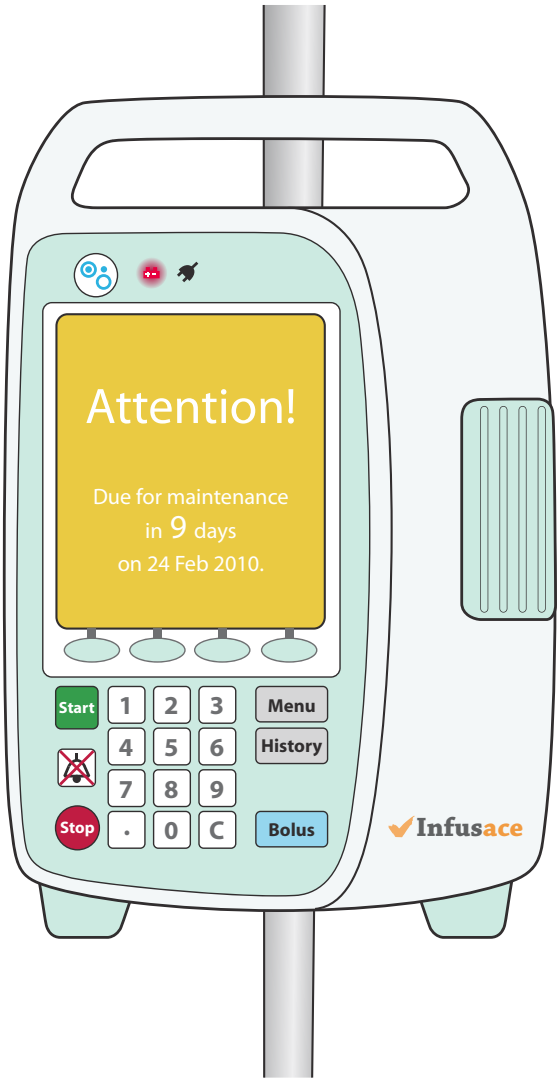
Issues

- Maintenance prompts are often provided by stickers, which get worn away and lost in the visual clutter of the device.
- Items that require regular access, such as batteries, cannot be easily accessed by maintenance staff.



Recommendations

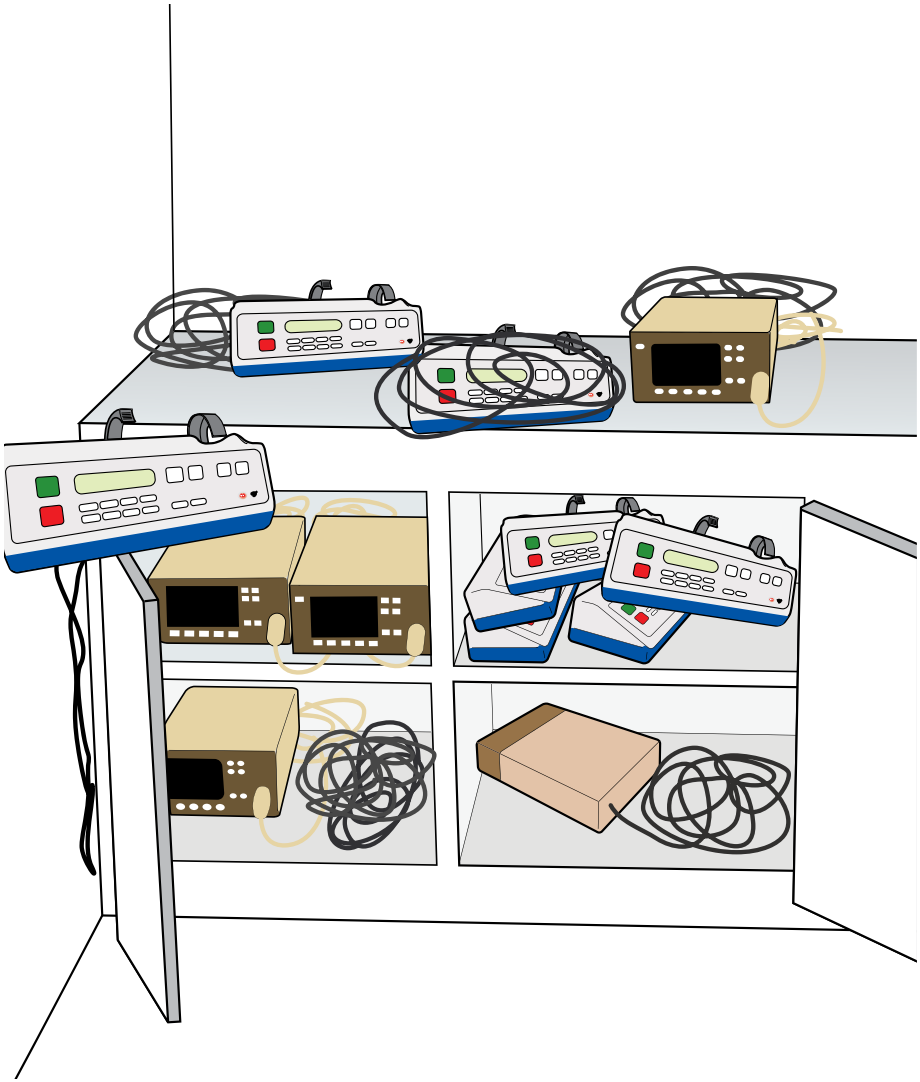
- Manufacturers should consider a configuration option to enable devices to prompt the user with an on-screen warning when they are due for maintenance. Consider providing users with a countdown to the maintenance date.
- Device designs should facilitate simple workshop maintenance procedures such as changing batteries and cleaning sensors. Simple designs create simple maintenance procedures, and minimising part numbers can also make repair easier.



1.15 Device storage

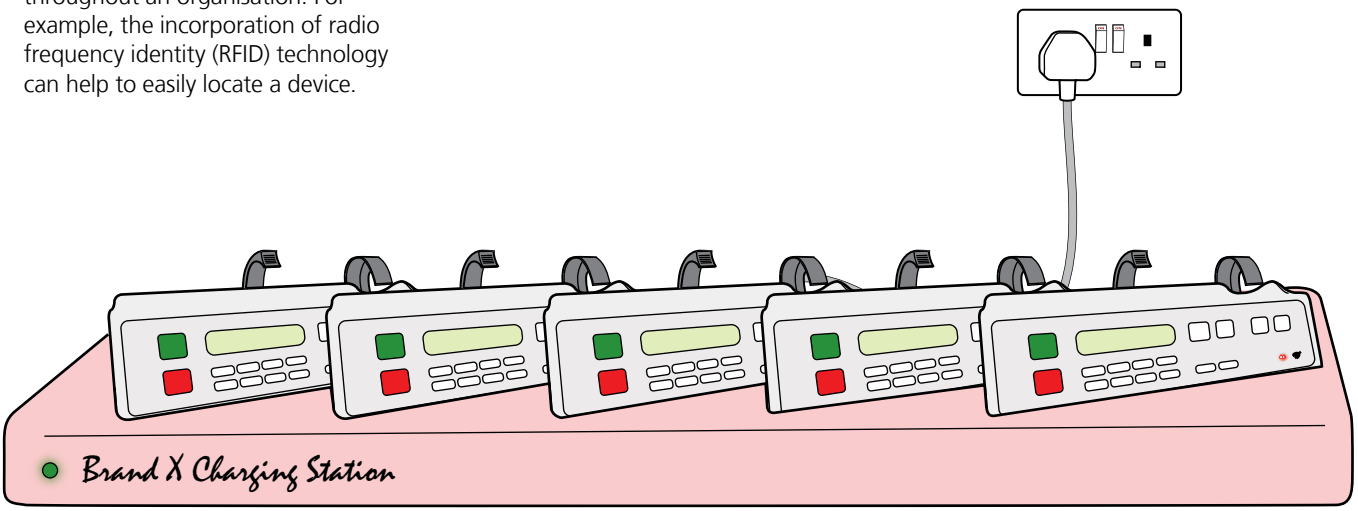
Issues

- Device storage can be disorganised and chaotic, leading to device mismanagement.
- Devices are left unplugged when not in use, leading to flat batteries.
- Devices may become ‘lost’ or misplaced, as patients move around hospitals with their devices.



Recommendations

- Manufacturers should consider how the equipment is stored when not in use and ways of ensuring devices are plugged in whilst in storage. Better designed storage providing charging stations may help to ensure that the devices are stored safely and in a charged state, ready for use.
- Organisations should have equipment libraries where devices are sent to be serviced, maintained and stored.[1]
- Consider ways of tracking devices throughout an organisation. For example, the incorporation of radio frequency identity (RFID) technology can help to easily locate a device.



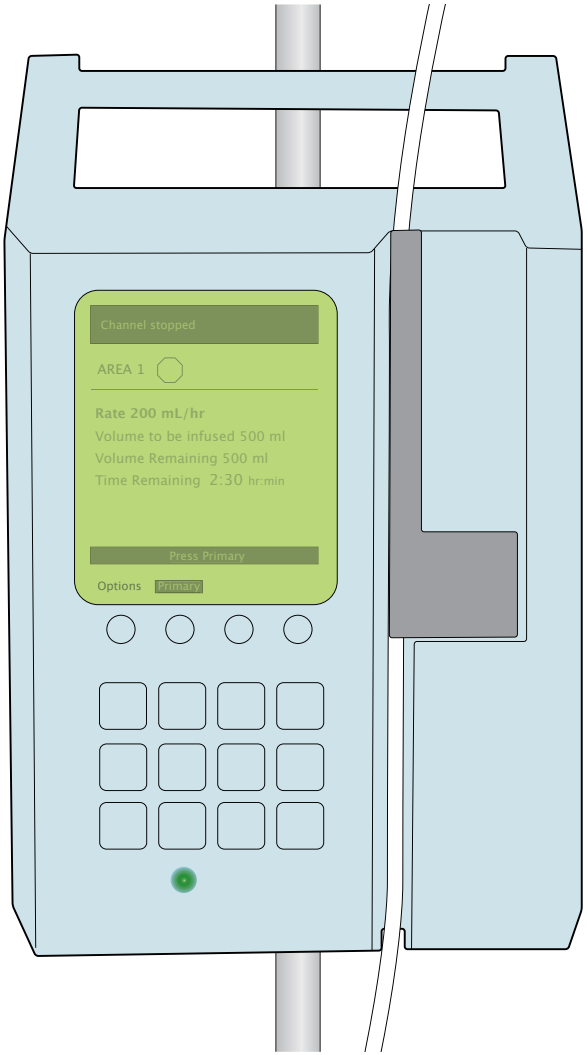
2

Software design

2.1 Layout – essential information

Issues

- Users cannot readily find the information they require as emphasis is given to less important data.
- The current status and operational settings of a device may be unclear.
- The units of the flowrate may not be displayed or may be unclear.
- Screen layouts are cluttered with information clustered around the edges of screens.



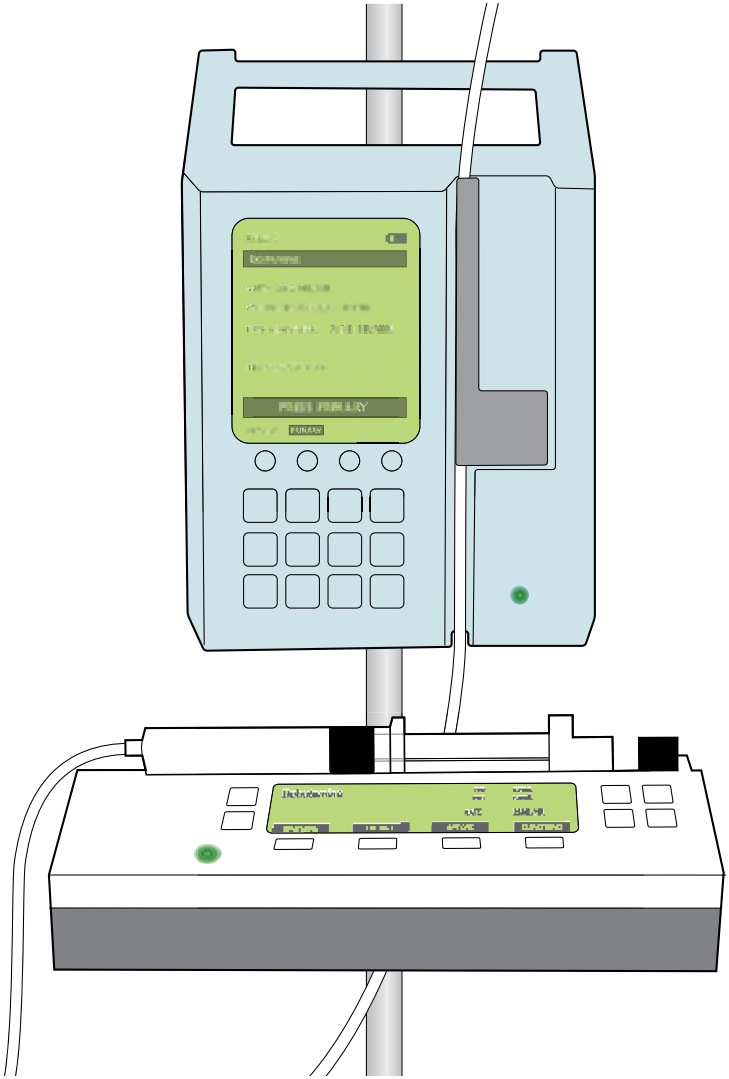
Recommendations

- Highlight the information most readily required by the users of the device. They need to be able to see:
  - drug name and concentration (where applicable);
  - flow rate;
  - device status (infusing/stopped/ standby);
  - time remaining/volume to be infused;
  - volume infused/total volume infused;
  - mode of delivery – continuous, PCA, KVO;
  - power supply (mains/battery, battery life);
  - occlusion pressure levels.
- There should be a clear visual indicator of whether a device is on, and what it is doing.
- Units should have the same prominence as the numerical display of the flowrate.
- Key information should be positioned in the centre of the screen.

2.2 Fonts and text

Issues

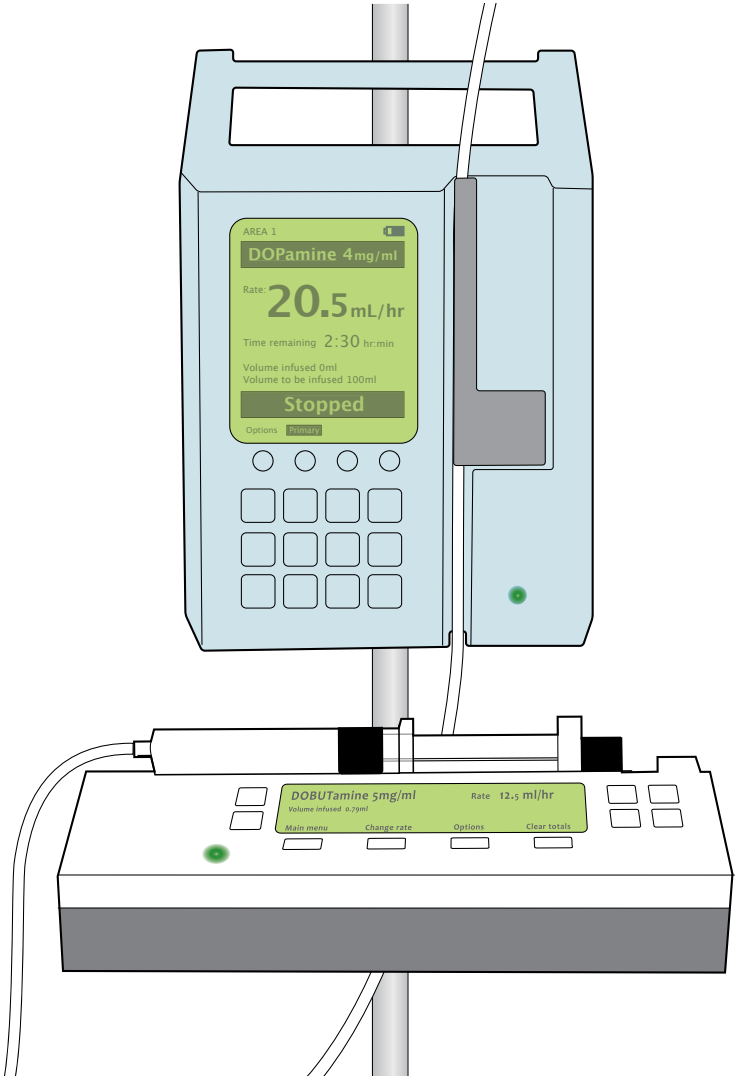
- Text may be written in a small font size that is difficult to read.
- Sentences are written in capital letters, which are harder to read.
- Similar words/drug names may be easily confused with each other.
- Terms are used that may be misunderstood or confused, e.g. ‘proximal and distal’.
- Abbreviations may be confusing and unclear, e.g. IU = units, mcg = micrograms.



Recommendations

- Use clear, legible, anti-aliased* fonts, in large font sizes. Numbers after a decimal point should be in a smaller font size.
- Text should be written in sentence case where a capital letter is only used at the beginning of the sentence.
- Use 'TallMan' lettering to distinguish between drugs with similar names, e.g. DOPamine and DOBUTamine.[24,25]
- Avoid using terms such as 'proximal' and 'distal' that may not be understood. Terms like 'downstream' and 'upstream' are better.
- Use clear, simple language that can be easily understood.

* Distortion occurs when high resolution graphics are displayed on a low resolution screen. Anti-aliasing is the technique of minimising this distortion and thereby maintaining legibility.



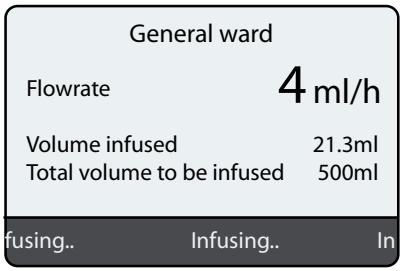
2.3 Device configuration

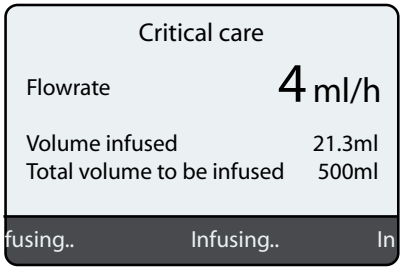
Device configurations enable default rate, volume, air and occlusion detection, medicine settings and displays to be set for different patient types and clinical areas of use. Devices may also be configured for continuous, patient control, intermittent and background infusion.

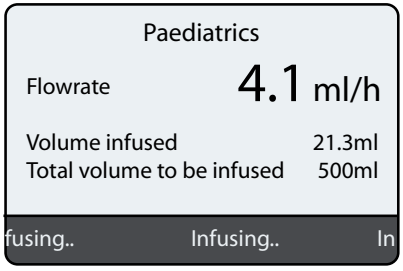
From time to time, device manufacturers release new versions of device software to correct software faults and provide new functionality. These settings assist the safe and effective use of these devices for the application for which they are intended.

Issues

- It is often not clearly displayed which software release is operating in the device.
- The default settings of each configuration are not always displayed or understood by users.
- Infusion devices may move between clinical areas and be used for different patient groups. The configuration, personality and software version that helps to ensure safe use in one clinical area and group of patients, may increase risk in another area with different patients. Devices are often moved to different patients and areas that require other personalities.

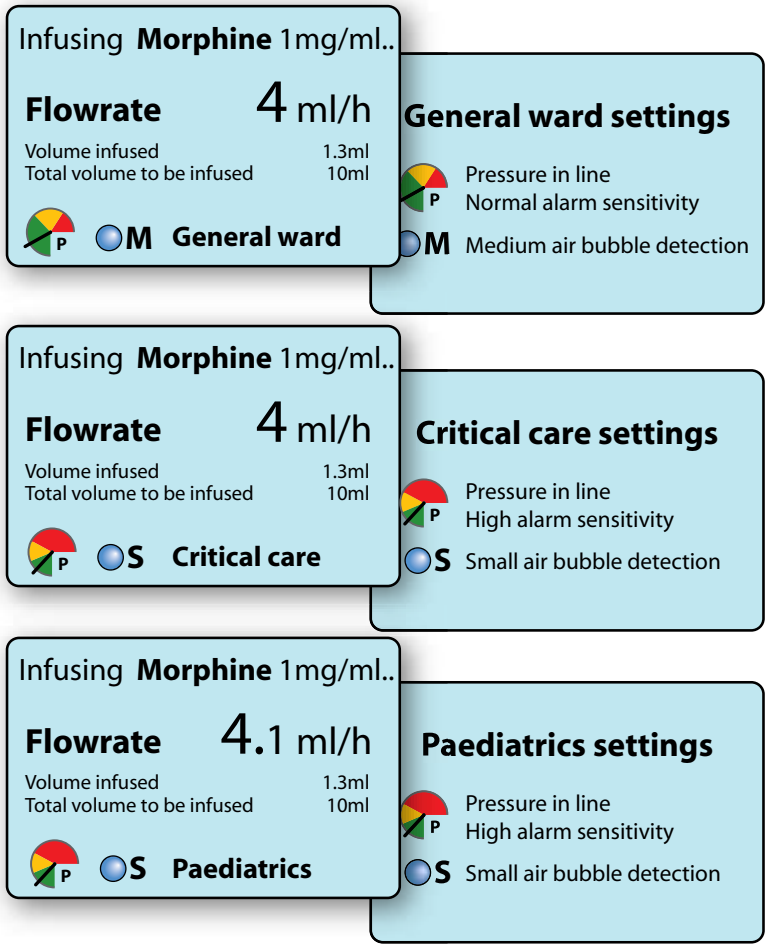






Recommendations

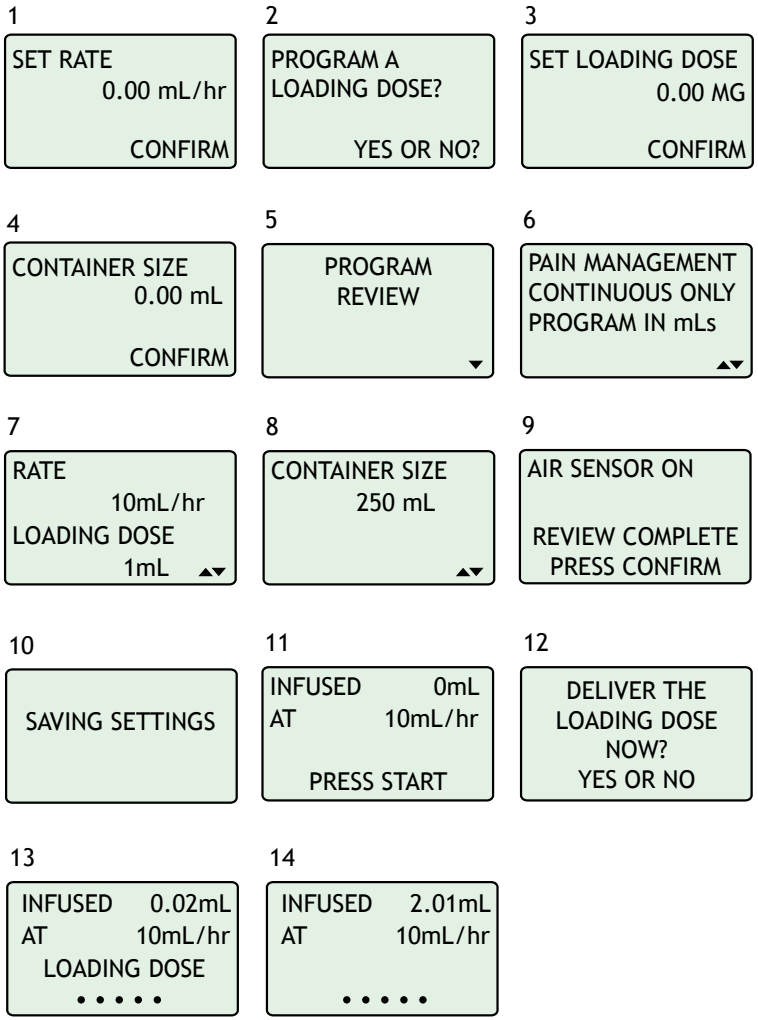
- The software version should be displayed when the device starts up. The configuration setup should be clearly displayed on the main screen.
- The default settings of the different configurations should be made clear to the user.
- Organisations should give significant consideration to the way that device configurations are managed. If devices are frequently moving between different care areas they may wish to consider not having different configurations and having one standard setting instead. Alternatively, an organisation may wish to allow authorised users as well as clinical engineering staff to be able to change the settings. Manufacturers should discuss the different options with the organisation to best provide for their varying requirements.



2.4 Setting up an infusion

Issues

- Instructions can be unclear or hidden.
- Programming may be a lengthy and unwieldy process, with very little information conveyed to the user as to the end of the process.
- Prompts and road maps are absent, leaving the user lost and confused.
- The user may become overwhelmed by too many options being displayed.
- It can be unclear what mode a device is operating in, which may have completely different settings assigned to it. Modes can also be very difficult to exit or change.

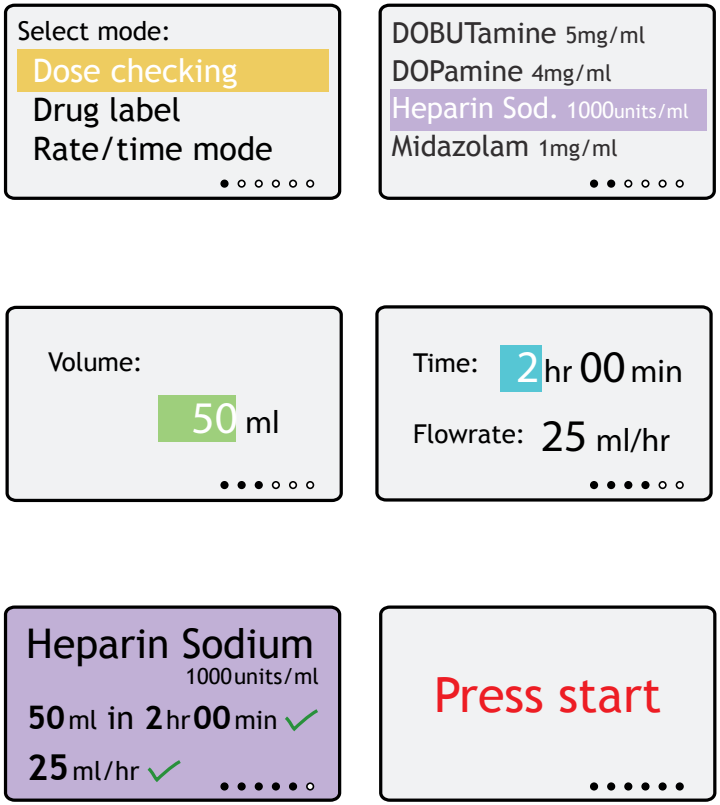


Recommendations

The order of basic information entry should be:

1. Select mode (where appropriate);
2. Select drug (label AND dosage checking);
3. Enter volume;
4. Enter rate of administration, ml/h, or time to be delivered, hr:min.

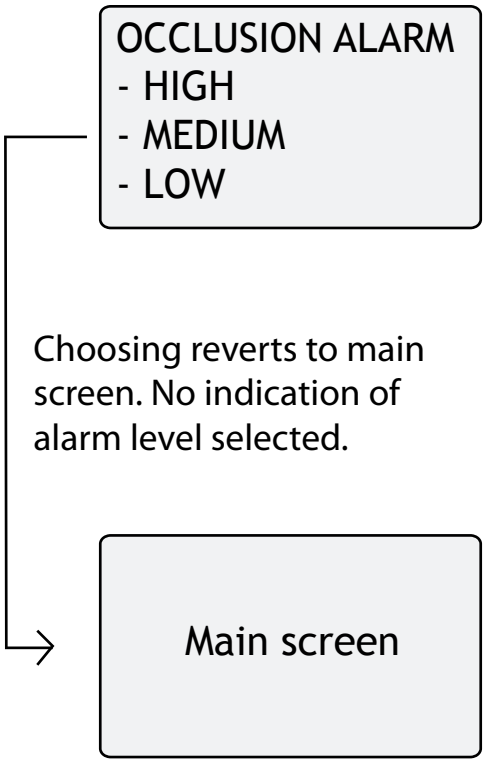
- Instructions should be clearly highlighted on screen, particularly those requiring the user to press start or stop.
- The number of steps required should be kept to a minimum. Indicate to users how many steps there are, and how far through the programming process they are. Once the settings have been made there should be a final review and confirmation before the new settings are activated.
- Use prompts and menus to cue the user about important steps.
- Show only the minimum options necessary.
- There should be clear indicators as to what mode the device is operating in. It should be very clear how to exit or change the mode.



2.5 Feedback and communication

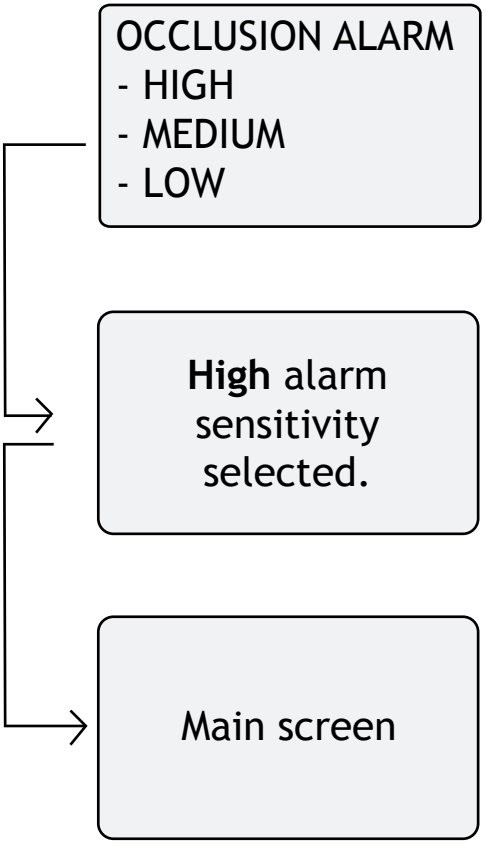
Issues

- Ambiguous displays may lead users to believe that the device is performing an action that it is not.
- Users may become confused about whether an action has been carried out by the device.
- It may be unclear as to whether a button press has been registered by the device.



Recommendations

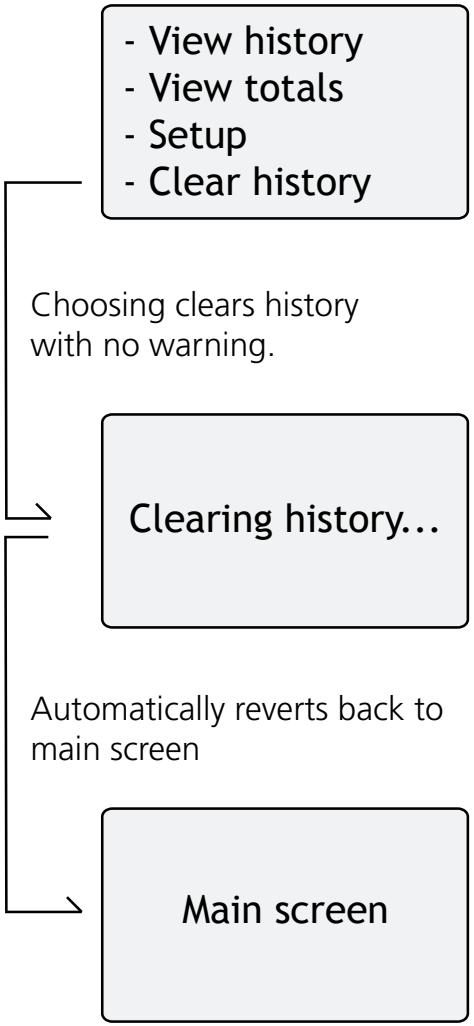
- Users should be given continual feedback as to what the device is doing.
- Users want to know that a command is being carried out. If it can't be carried out then they should be informed why.
- Buttons should give tactile feedback to the user, to confirm that the button action has taken place.
- Audio as well as visual and tactile information would allow feedback in most environments.



2.6 Error recovery

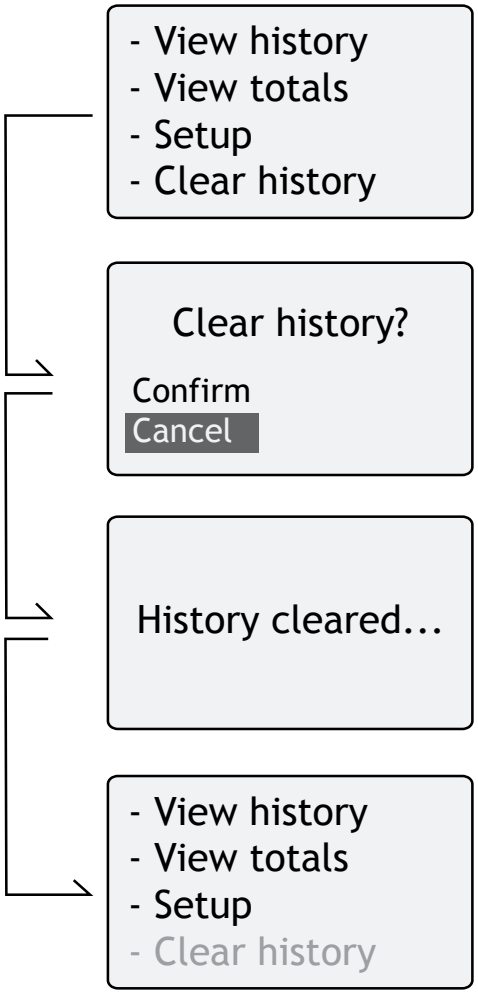
Issues

- Users may not be able to exit from an error message, resulting in them turning the device off and on again.
- Users cannot rectify a mistaken key press.
- Users cannot exit back to the main screen without changing settings.
- Data can be easily deleted in error.
- Users cannot review their choices before starting the infusion.



Recommendations

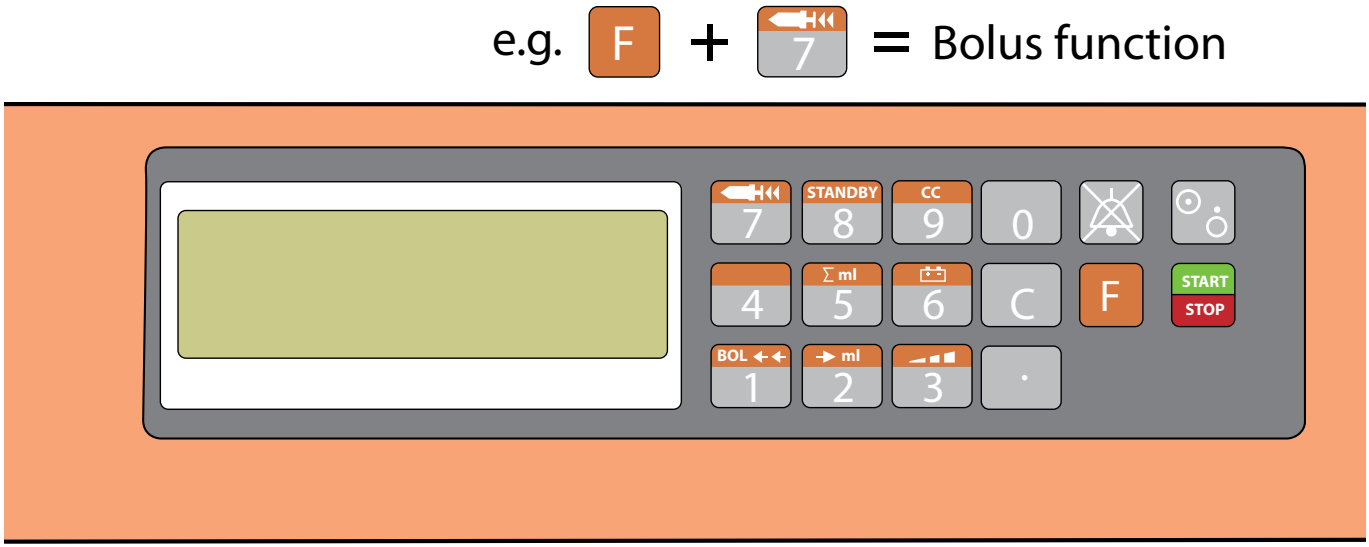
- There should be clear instructions on-screen as to how to rectify an error.
- It should be clear to users how to rectify any mistaken key presses and return to previous screens.
- There should be a way of returning to the main screen without changing any settings. This will encourage users to explore the system and understand the system. If any settings have been changed the user should be clearly notified.
- Where an action has potentially dangerous consequences, such as deleting data such as the patient history, the default action should be the cancelling option.
- Users should be able to review their choices before beginning an infusion.



2.7 Shortcuts and multi-function buttons

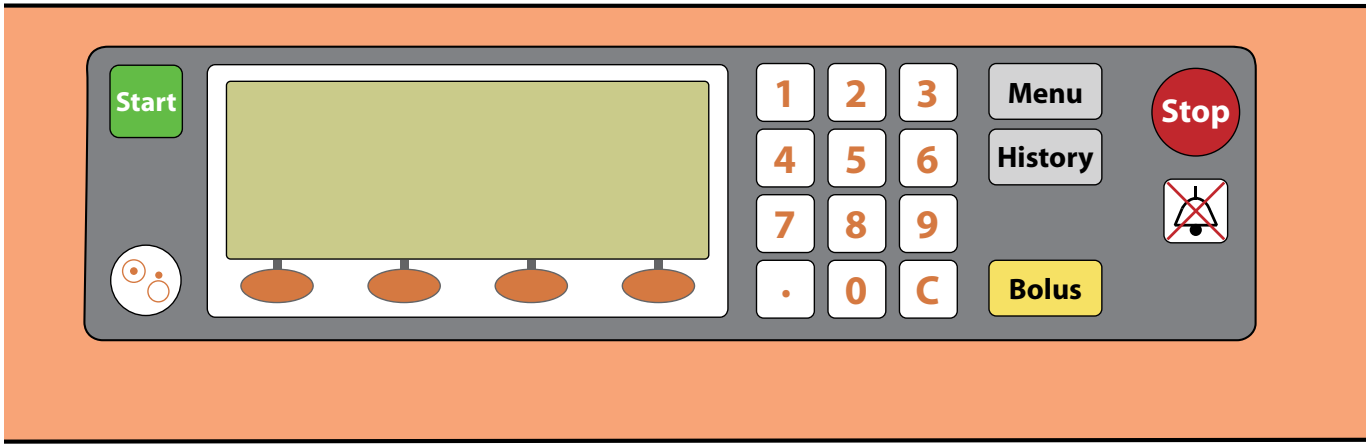
Issues

- Shortcuts may create confusion amongst users who are not familiar with them. It also discourages users from exploring the device features, for fear of causing undesirable consequences.
- Hidden shortcuts may be inadvertently activated without the user's knowledge and cause changes to the infusion.
- Buttons that are labelled with two symbols can be confusing and hard to identify.



Recommendations

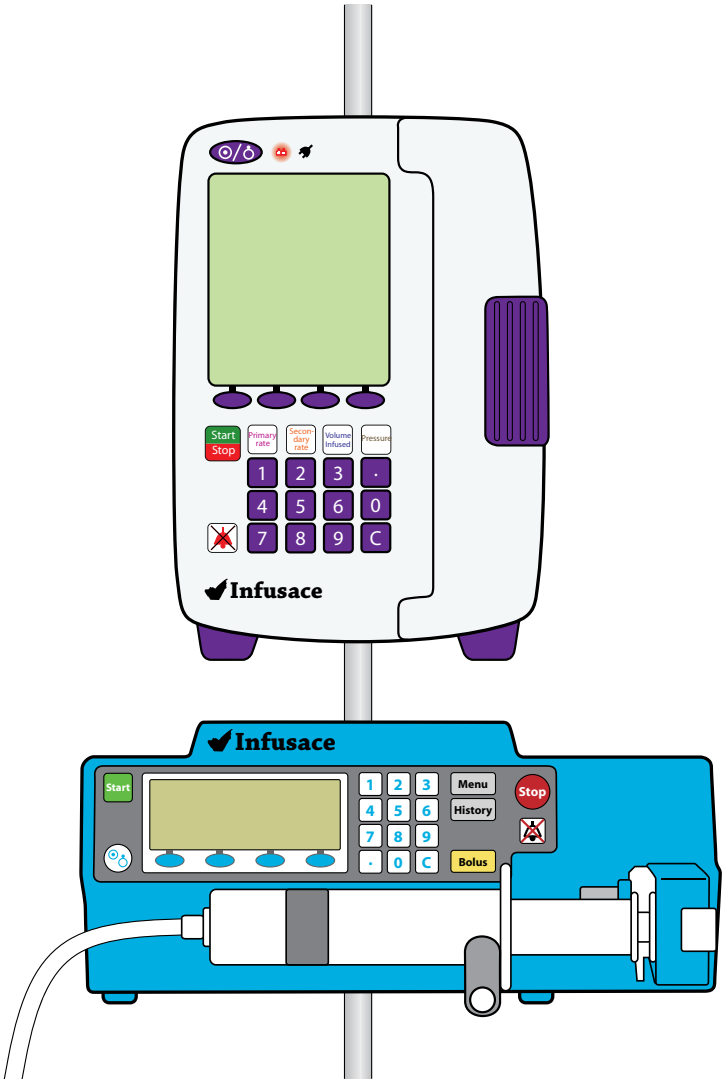
- Shortcuts should be avoided where possible.
- Where shortcuts must be used, the function should be confirmed by the user before operating. It should also be clear how to perform an action through the longer route.
- Buttons should have one function only and be clearly marked and identifiable.



2.8 Interface consistency

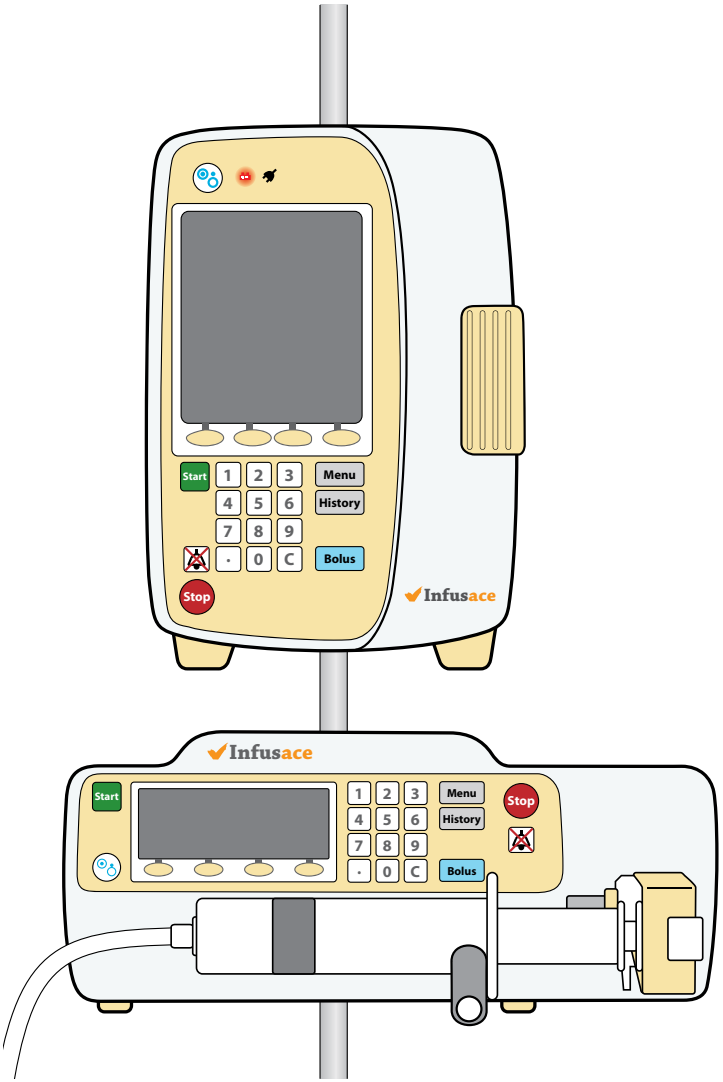
Issues

- The device may behave differently in different areas of the software.
- Devices from one manufacturer may have differing interfaces, requiring two different interfaces to be learnt by the user. This may cause confusion and error in operation, and may also lead to additional time being spent training users.



Recommendations

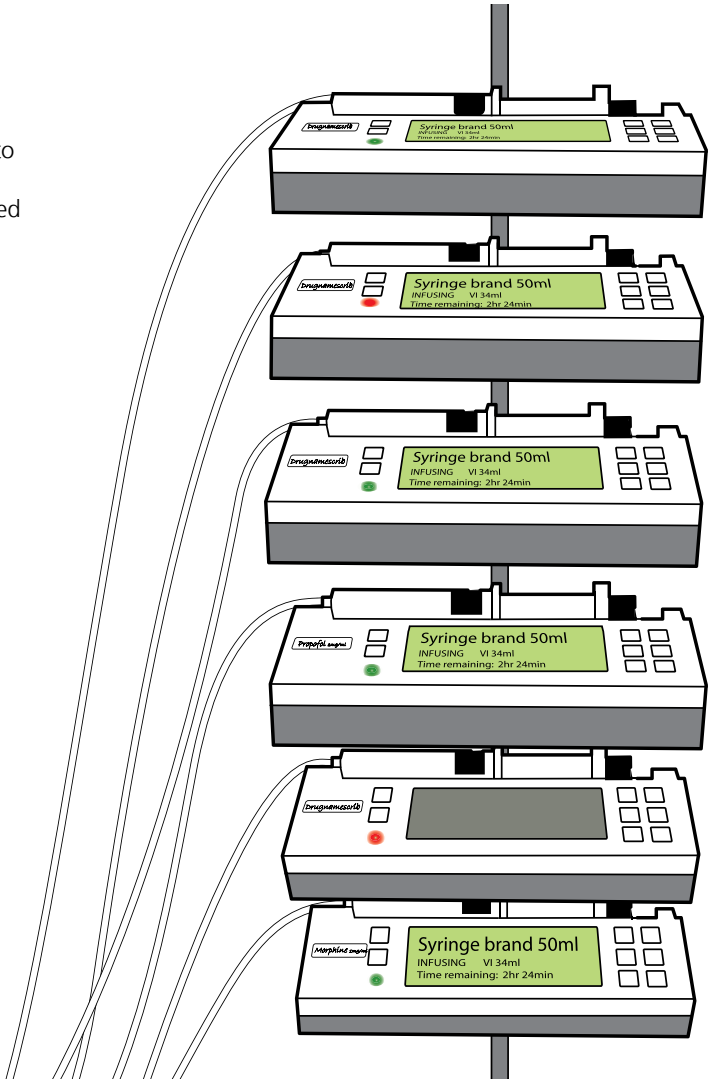
- There should be the same user interface and operation in all areas of the software. This means that where there are common features and functions, the same set of actions should produce the same response from the device throughout the software.
- By applying consistent interfaces across a range of products, users are able to transfer a set of skills from one device to another.



2.9 Medicine labels

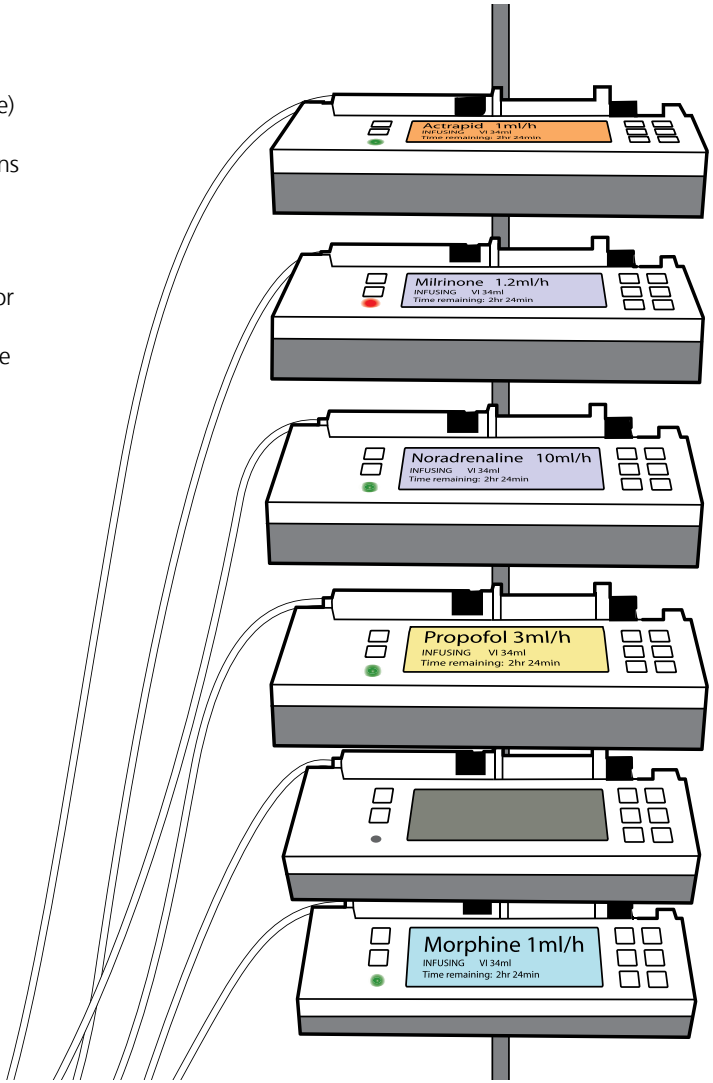
Issues

- There is risk of device misallocation in a multiple device infusion system.
- Sometimes paper labels are attached to devices to identify individual infusions, but these paper labels must be removed at the end of each infusion treatment and are not always easily read.



Recommendations

- Medicine label software (confusingly sometimes called drug library software) enables medicine names to be clearly displayed on the infusion device screens to help minimise device misallocation.
- It is important for users to be made aware of the difference between medicine label software and Dose Error Reduction Software (DERS). Device suppliers should use the term medicine label software rather than medicine library, to make the distinction clear.



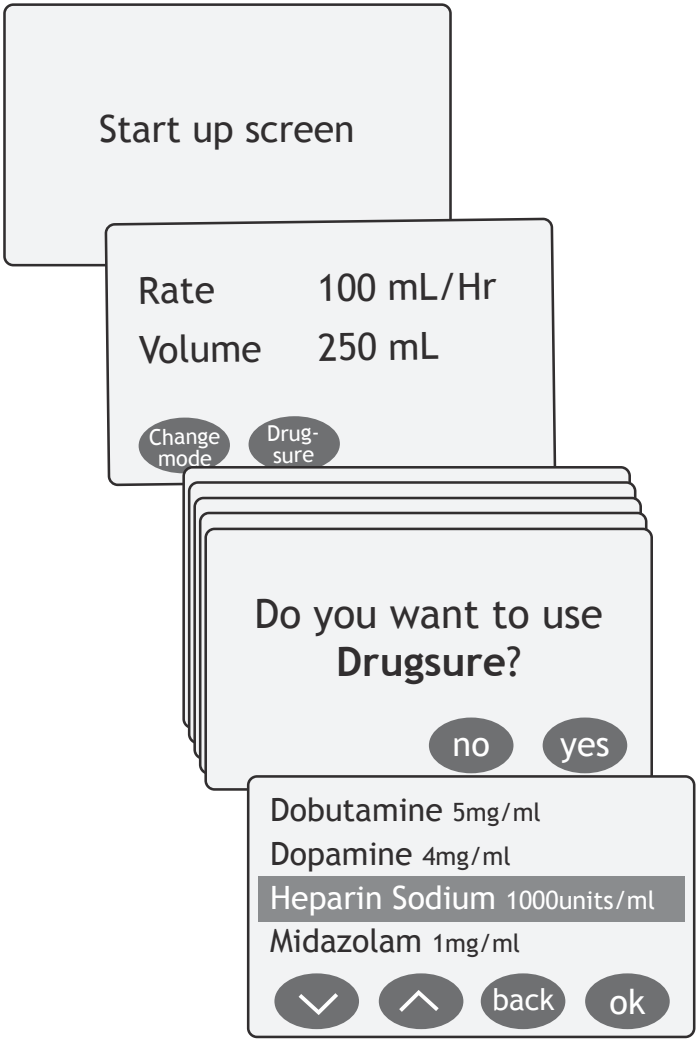
2.10 Dose Error Reduction Software (DERS)

DERS alerts the user if they try to over or under infuse a specified infusion.

The user will be alerted to potential over or under infusion and will have the opportunity to select a safer rate of administration for the patient.

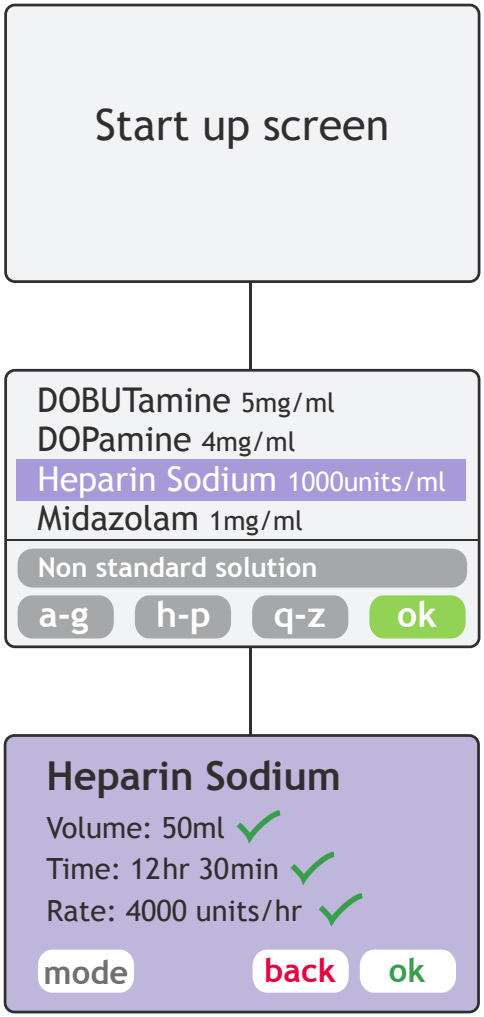
Issues

- Users may think that the device is using DERS when it is displaying a medicine label.
- Devices with DERS usually have default configurations with the DERS switched off. Consequently the DERS may not be used on these devices in practice.
- Users are presented with traditional rate and volume of infusion screens at start-up and have to take separate actions to switch DERS on.
- Programming and configuring DERS can be a time-consuming and tedious process.
- It can be hard to find particular medicines in a long medicine library.



Recommendations

- The device should clearly indicate whether it is using DERS or a medicine label.
- The DERS should be simple to use, and on as the default option. When the device starts up, the user should be presented with the DERS medicine selection screen. Users should have to select the non-standard solution in order to obtain the traditional 'rate' and 'volume to be infused' screens.
- The device should have comprehensive log-analysis software, where it monitors the number of occasions where DERS alerts have been activated, and what percentage of these have resulted in a revised rate of administration. It should also monitor the percentage of infusions where DERS is switched on and off.[26]
- It should be possible to develop and edit medicine libraries and DERS on a spreadsheet-based system and transfer this information to the device.
- Manufacturers should give consideration to how the medicine libraries are best navigated by users.



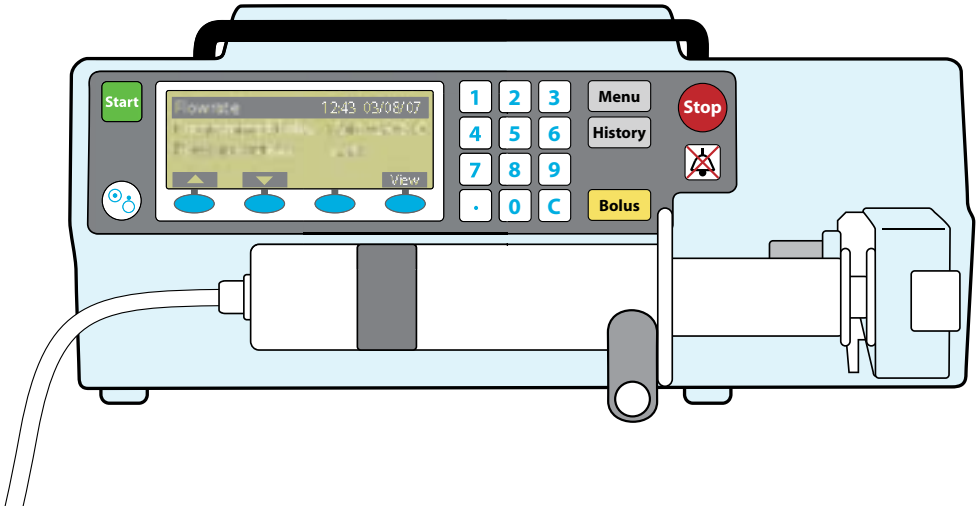
2.11 Data logging

Data logging records individual key presses and other operating events of the infusion device.

Review of this data is helpful in the event of a patient safety incident to determine how the device was operated up to and beyond the incident.

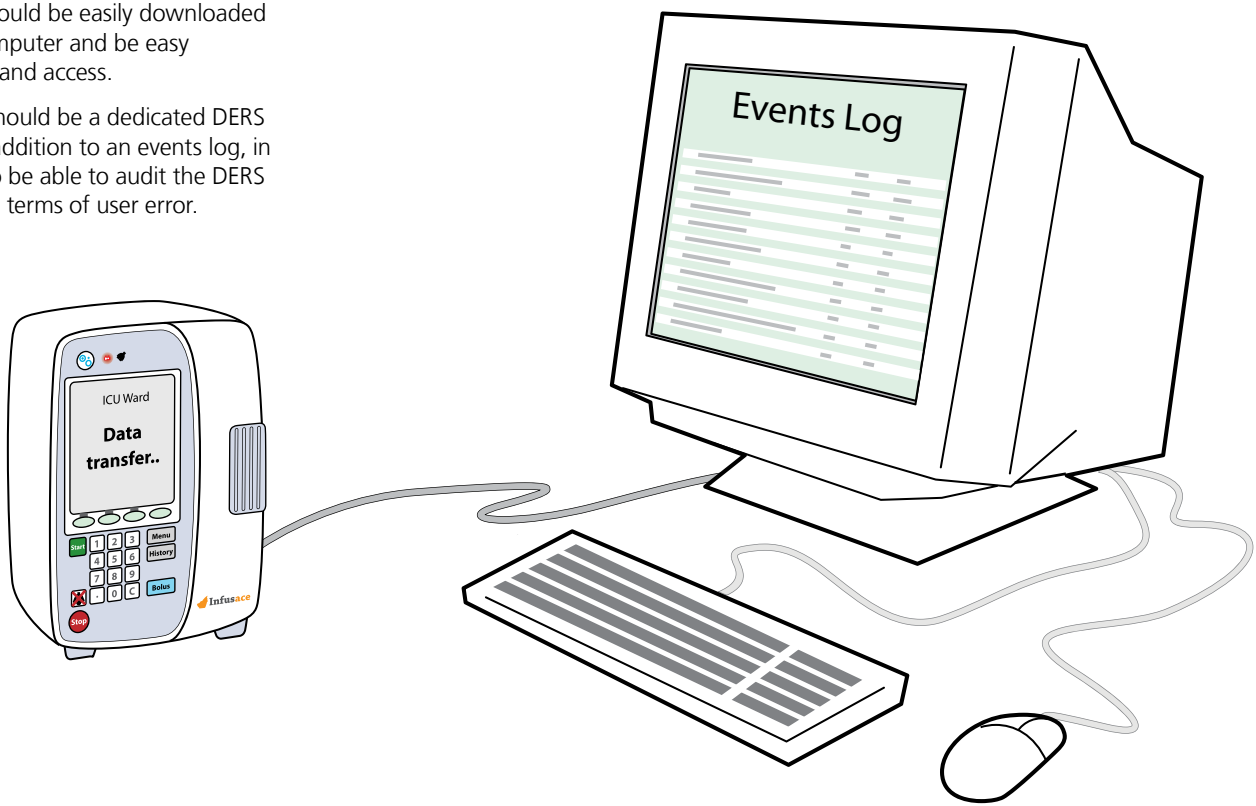
Issues

- Devices may store insufficient amounts of data.
- Data may be inadvertently lost by pressing the wrong button.
- Data can be hard to access and awkward to view.
- Key press data is not separated from DERS logging data.



Recommendations

- Devices should store at least six months worth of data to enable audit learning.
- When data are being deleted a confirmation message should come up to confirm the deleting action.
- Data should be easily downloaded to a computer and be easy to read and access.
- There should be a dedicated DERS log, in addition to an events log, in order to be able to audit the DERS alerts in terms of user error.



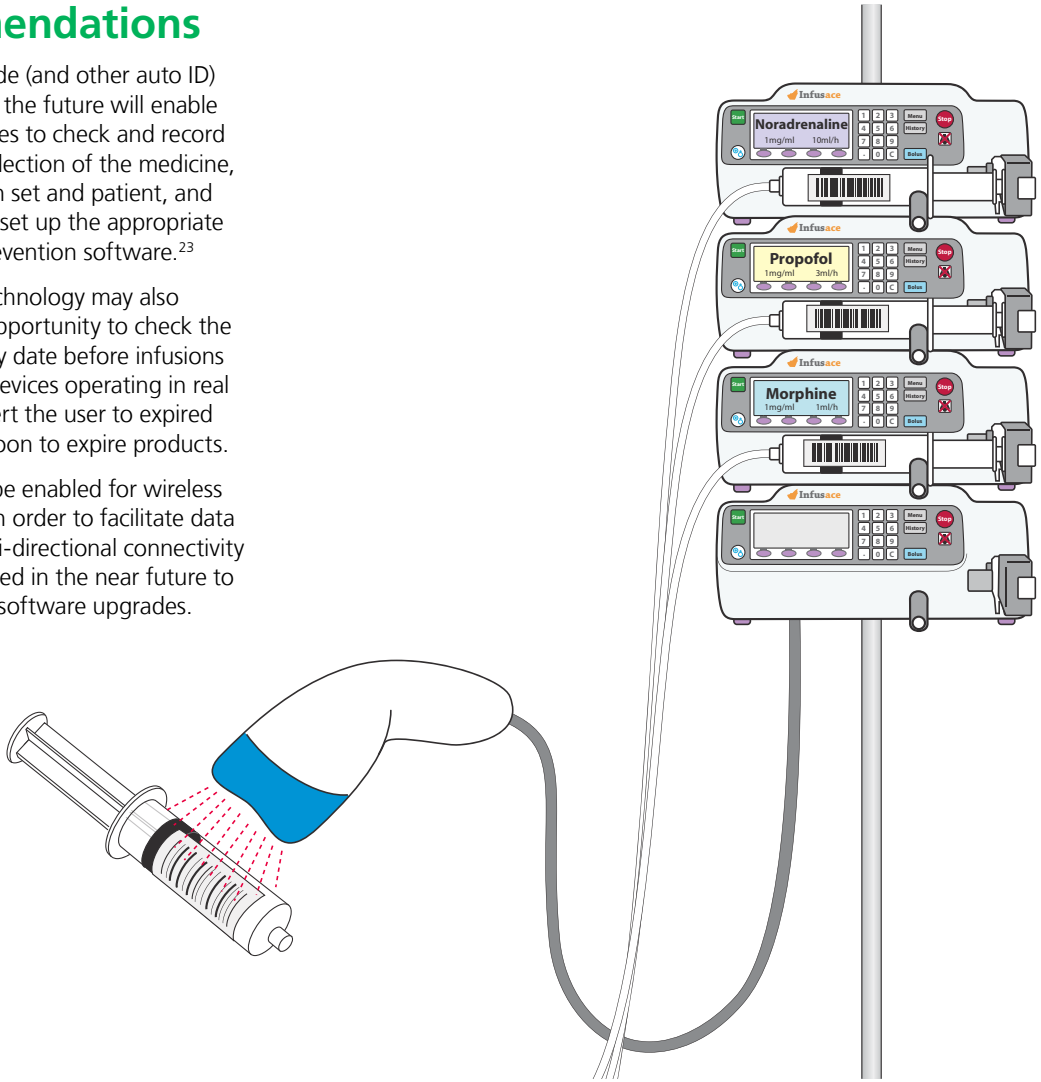
2.12 Medicine identification

Issue

- Infusions may be prepared in ward areas or supplied ready-to-administer. Users have to correctly select and connect the correct medicine. The infusion device and administration set must be connected to the correct patient and programmed accurately.

Recommendations

- Use of bar code (and other auto ID) technology in the future will enable infusion devices to check and record the correct selection of the medicine, administration set and patient, and consequently set up the appropriate dose error prevention software.[23]
- Use of this technology may also provide the opportunity to check the product expiry date before infusions commence. Devices operating in real time could alert the user to expired products or soon to expire products.
- Devices may be enabled for wireless connectivity in order to facilitate data downloads. Bi-directional connectivity will be expected in the near future to enable smart software upgrades.



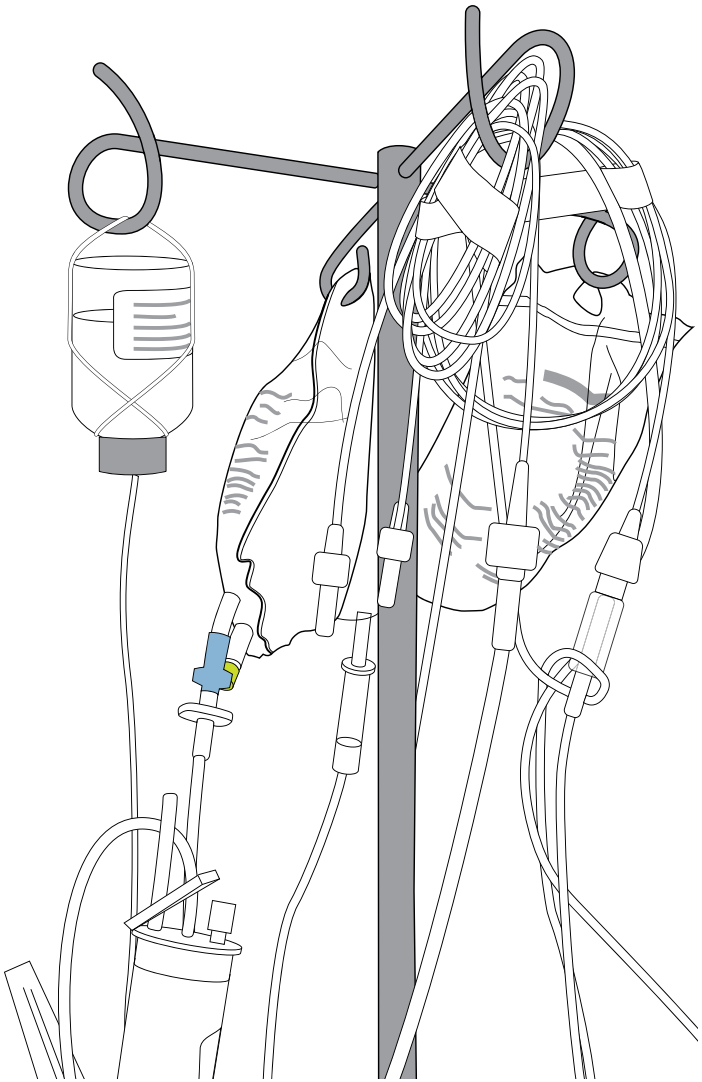
3

Administration sets

3.1 Administration sets

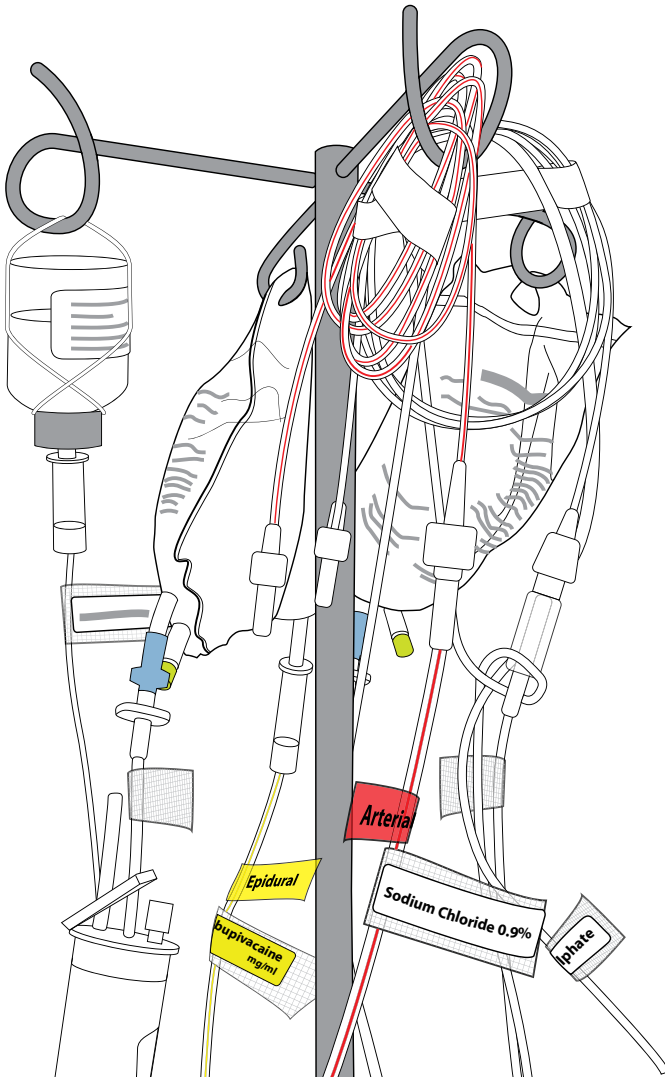
Issues

- Infusion systems may be very complex in practice. It is often difficult to identify the infusion container and infusion line with the corresponding infusion catheter.
- It can be easy to confuse administration sets. This can be especially problematic where the sets are for different routes of administration.
- It can be confusing as to which administration sets are compatible with which devices.
- Administration sets vary in their functionality in order to infuse different products. However, these differences may not be made clear.



Recommendations

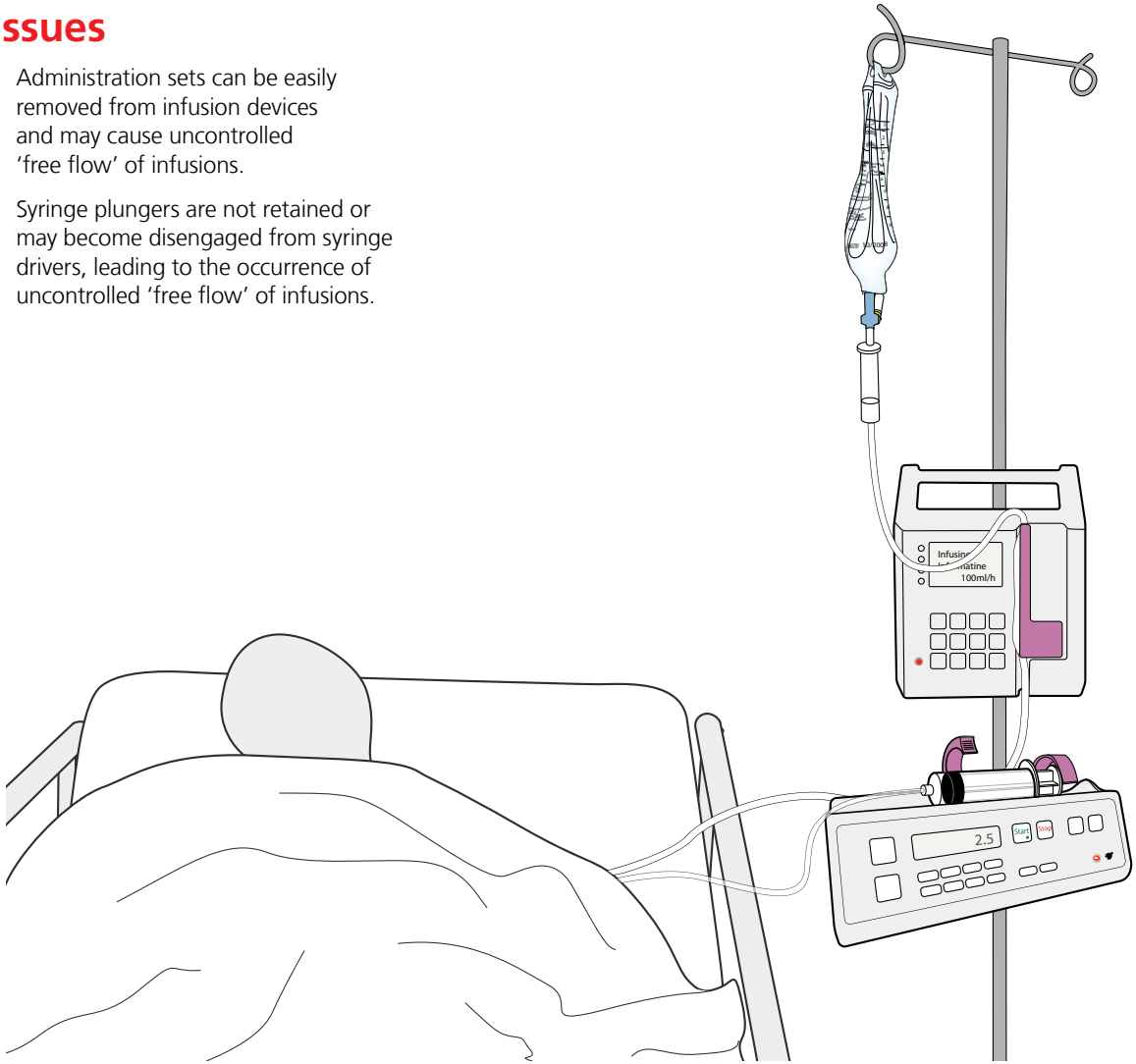
- Consider the use of colour for different routes of administration. Spinal/epidural infusions should use the colour yellow, arterial lines should use red, and purple should be used for enteral feeding.
- Administration sets to be transparent or sufficiently translucent so that the interface of air and solution and the passage of air bubbles can be easily observed.
- Manufacturers should consider the use of different connectors on their epidural administration sets.[16]
- Manufacturers should consider including medicine labels with their administration sets, in order to identify the date and time the infusion was commenced.
- Administration sets should clearly specify the devices with which they are compatible.
- Infusion sets should clearly specify their intended use. This could be for general infusions, blood and medicines where special precautions are needed, e.g. low medicine absorption sets.



3.2 Anti-free flow systems

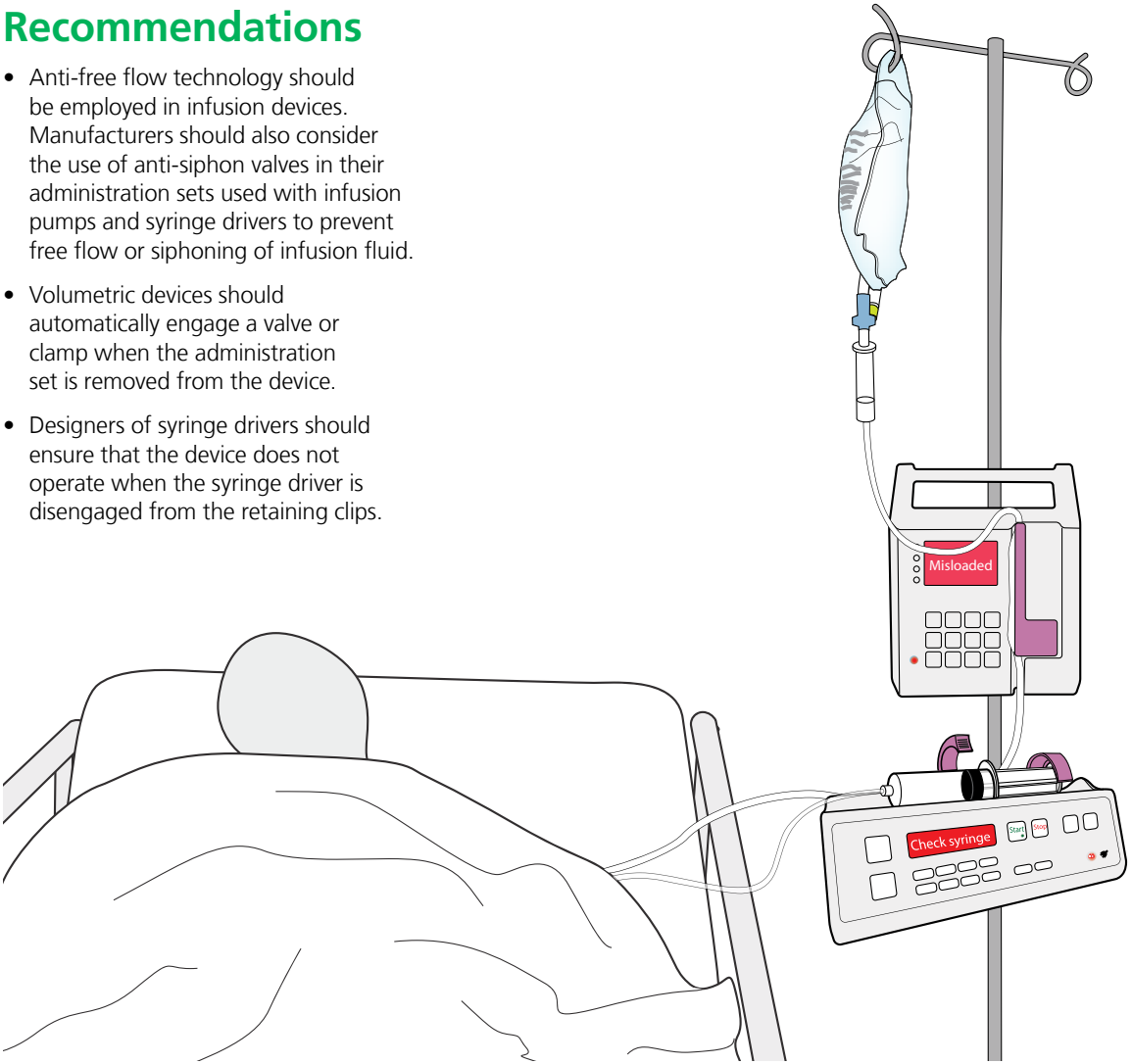
Issues

- Administration sets can be easily removed from infusion devices and may cause uncontrolled 'free flow' of infusions.
- Syringe plungers are not retained or may become disengaged from syringe drivers, leading to the occurrence of uncontrolled 'free flow' of infusions.



Recommendations

- Anti-free flow technology should be employed in infusion devices. Manufacturers should also consider the use of anti-siphon valves in their administration sets used with infusion pumps and syringe drivers to prevent free flow or siphoning of infusion fluid.
- Volumetric devices should automatically engage a valve or clamp when the administration set is removed from the device.
- Designers of syringe drivers should ensure that the device does not operate when the syringe driver is disengaged from the retaining clips.



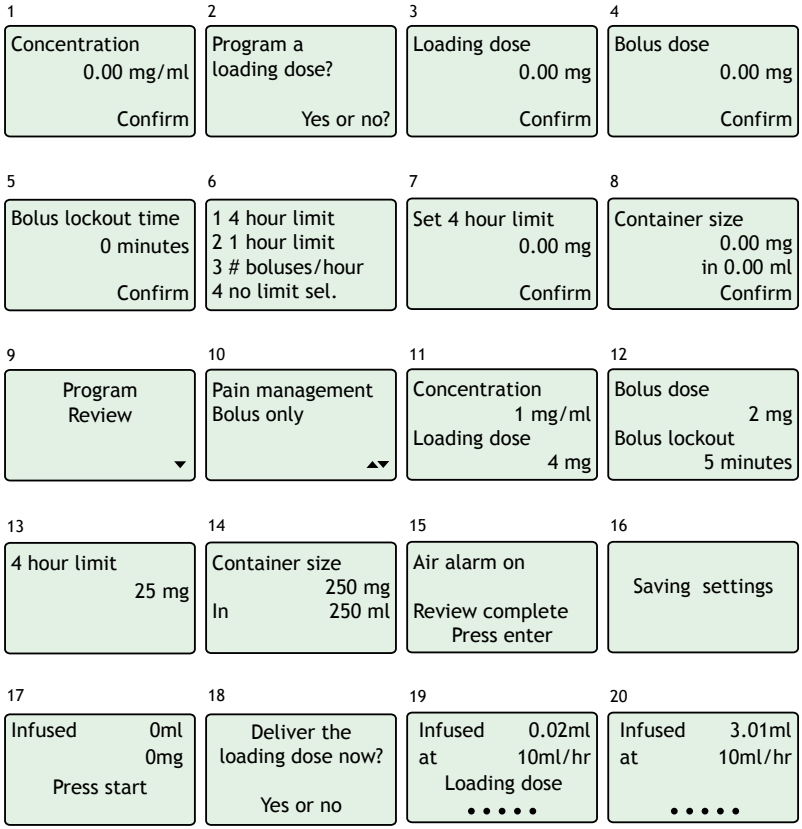
4

Specialist devices

4.1a Patient Controlled Analgesia (PCA) devices

Issues

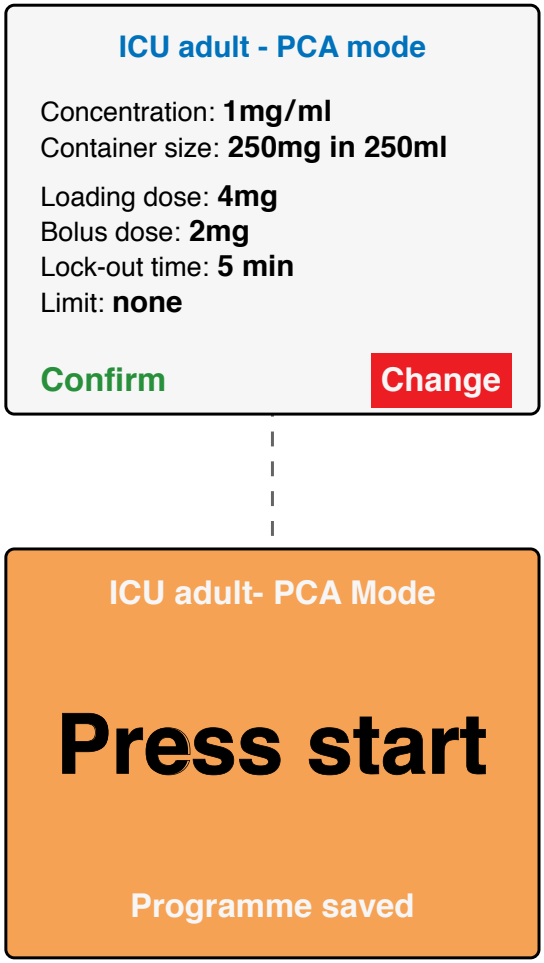
- Setting up an infusion can be a long and complex procedure.
- It may be unclear as to what mode the device is operating in.
- Open access to the PCA settings to all users may allow patient tampering.



An example of a PCA setup process

Recommendations

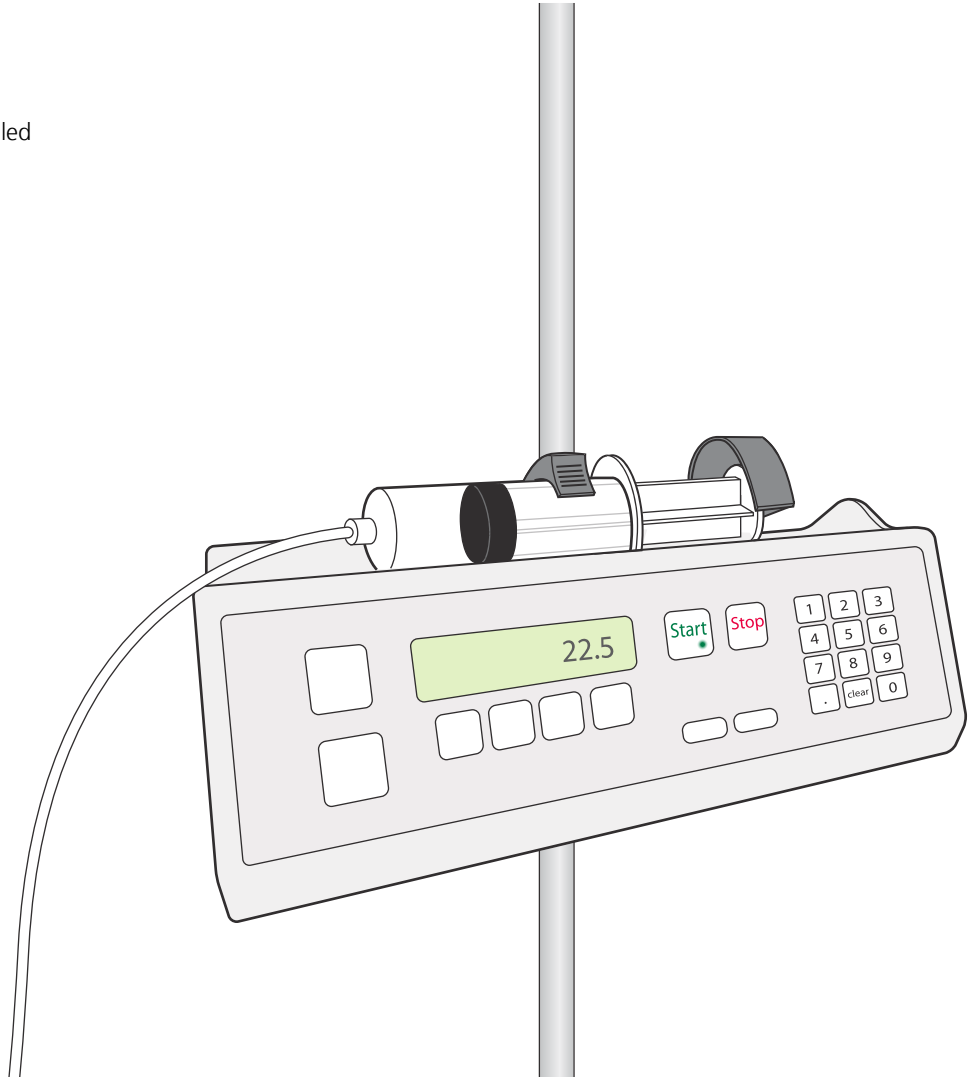
- Setting up an infusion should be a clear and simple procedure. Manufacturers should consider the provision of a default set-up for PCA devices.
- The device should clearly indicate whether it is operating in a 'Continuous', 'PCA' or 'Continuous & PCA' mode.
- Only specified staff should be able to change settings, e.g. with a pin code, whilst allowing other users to view the settings.



4.1b PCA devices – security

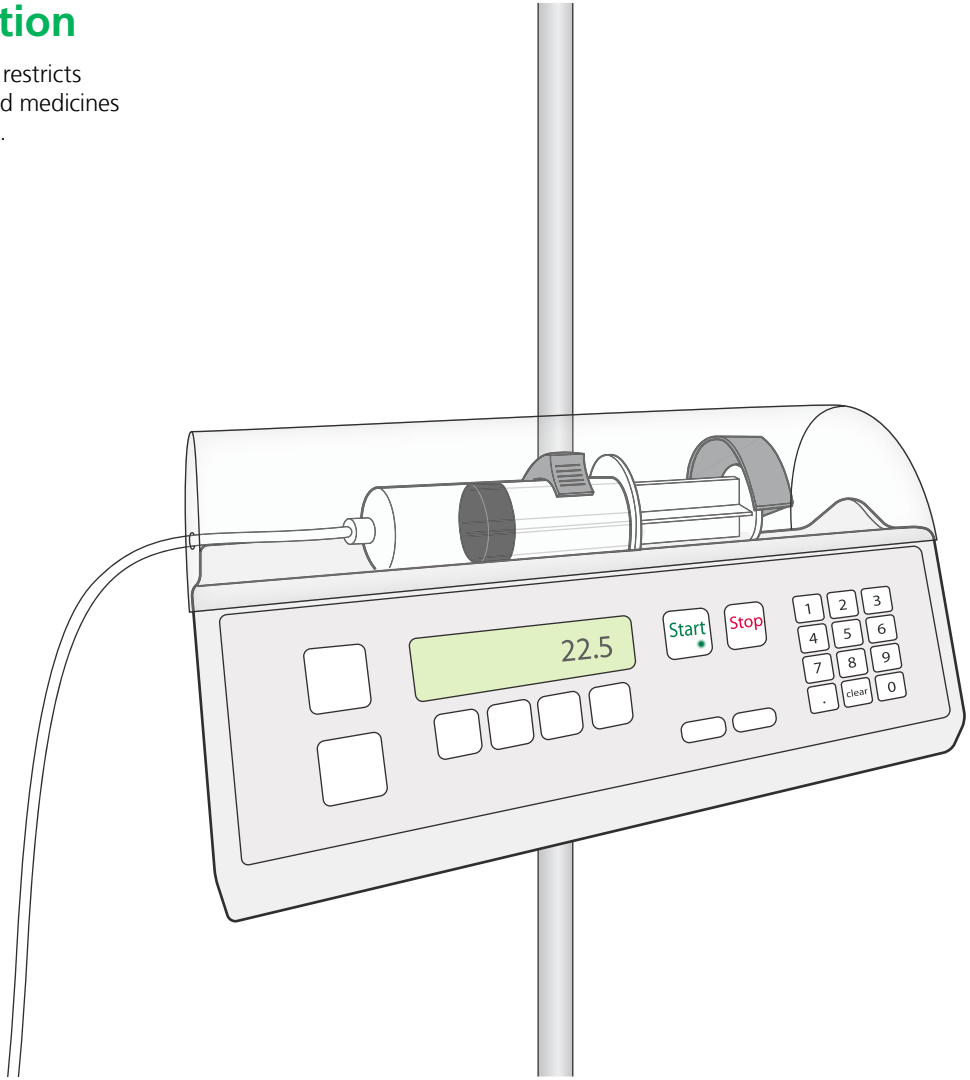
Issue

- PCA devices usually involve the use of opioid (controlled medicine) analgesics. Large infusions of controlled medicines may be subject to abuse.



Recommendation

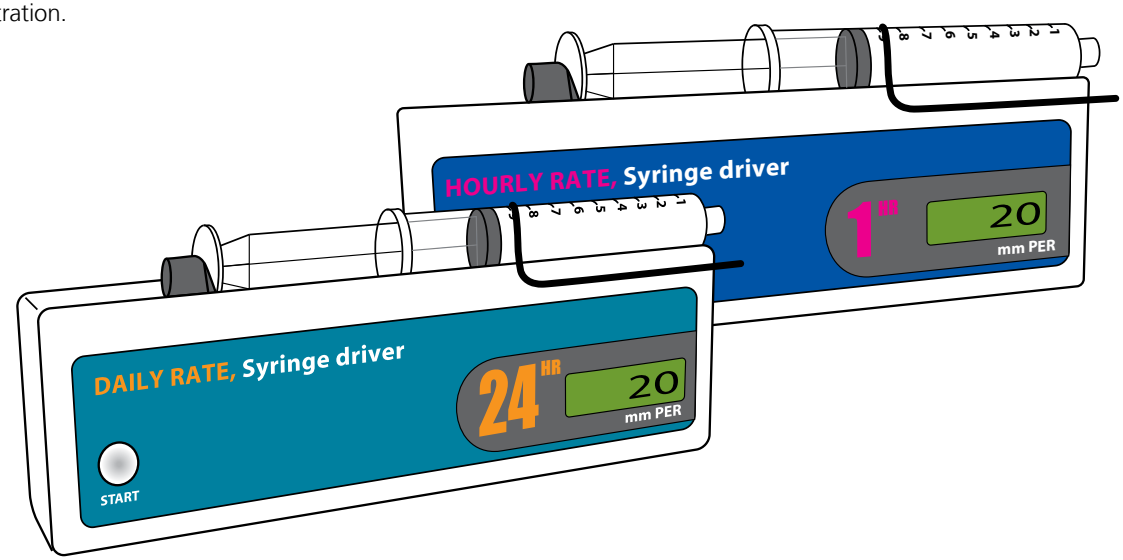
- The use of locked boxes restricts access to these controlled medicines and helps prevent abuse.



4.2 Devices for ambulatory care

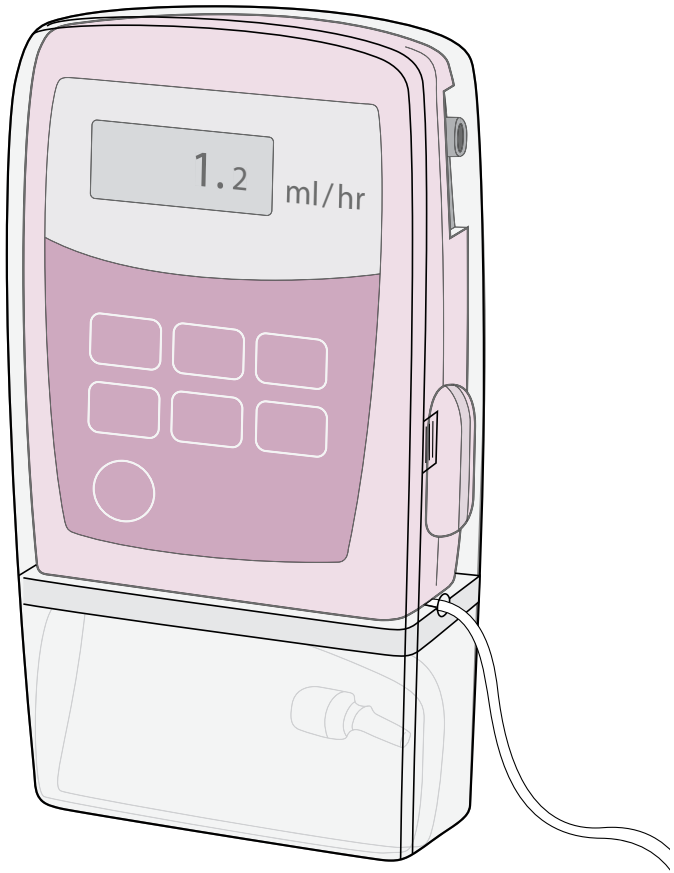
Issues

- Devices may be large and cumbersome, making them awkward and embarrassing for patients to carry around.
- It may be complicated to set up an infusion and be awkward to load the administration set.
- Outpatients require discreet devices, but flashing lights and audible alarms may cause distress by attracting unwanted attention.[22]
- Some devices are only licensed for subcutaneous administration and may be used inappropriately for intravenous administration.
- Some devices are programmed in mm of syringe plunger travel per hour, or per 24 hours. This can cause confusion and incorrect setting of the infusion rate.
- It can be hard to determine battery life and whether there is sufficient charge to complete the next infusion.
- Users cannot determine if an infusion has been properly administered or if any errors have occurred.
- Devices have not been designed with cleaning in mind and can cause infection control issues if soiled by patients.



Recommendations

- Ambulatory devices should be small and light for maximum patient comfort.
- It should be easy to set up an infusion and load the administration set.
- There should be options available for visual, audio and vibratory alert signalling. Alarm signals should be able to be silenced, with on-screen messages alerting the user to the cause of the alarm.
- Ambulatory devices should, at a minimum, be licensed for both subcutaneous and intravenous use.
- All infusions should usually be calculated and programmed in ml/hr.
- Devices should give an indication of battery life and alert the user to waning battery power. When setting up an infusion, the device should give an estimate of remaining battery time and be able to operate for at least 48 hours on one battery.
- Consideration should be given to incorporating a keypad lock or locked box to prevent interference from patients.
- In keeping with ward-based devices, ambulatory devices should have event logs to enable better infusion monitoring.
- Providing a closed cover around the device will help to prevent fluid ingress and enable better infection control.



Appendix 1: User testing

Recognising the link between design, human error and patient safety, the regulatory requirements for medical devices are placing an increasing emphasis on usability and other user-related issues.

For example, the US Food and Drug Administration require developers to apply human factors principles throughout the development of medical devices to identify, understand and address use-related hazards.[27]

The Association For The Advancement Of Medical Instrumentation has published a guide to the human factors design process for medical devices.[28]

New European medical device regulations specifically deal with usability. For instance, *IEC 6061-1-2: General Requirements for basic safety and essential performance*[29] specifies the usability requirements for the safety of medical devices. The collateral standard requires a 'usability engineering process' to be used during device design. IEC 60601-1-6 requires developers to keep comprehensive records to show that usability has been considered throughout the design process. This standard only covers electrical medical devices; however a new standard is due for publication that will supersede this. *IEC 62366: Medical Devices Application of usability engineering to medical devices*[30] will extend the requirement for manufacturers to consider usability to all medical devices rather than just electrical medical equipment. The NPSA will publish further guidance in a new publication on user testing in the development of medical devices during 2010.

Infusion devices testing methods

Infusion device design needs to take account of the range of users that will use the device, in terms of their individual skills, experience and training. It also needs to reflect the wide range of environments in which the device will be used, such as intensive care wards, ambulances, community hospitals and even the patient's home, to ensure it will be safe for all users and uses.

The main route to achieving this is to carry out user testing that replicates or simulates the range of scenarios and tasks for which the device will be used. Consideration should be given to both the hardware and the software, and the complete lifecycle of the device, including storage, cleaning, and handling, as well as programming.

Device manufacturers should develop their own methods for testing their infusion devices on users. The example outline that follows was developed from Sawyer 1997.[31]

Overall aims for the testing procedure

There are a number of core tasks that are critical for the safe use of infusion devices, including programming the device, and identifying that the correct infusion is being administered. The user test should be able to highlight any undesirable outcomes resulting from the design and to determine the best combination of design parameters. User testing should be carried out early in the design process so that any problems can be resolved with minimal cost. The use of early prototypes for user testing is strongly encouraged.

Method

Test on a representative sample of participants from the various end user populations. Establish appropriate testing scenarios that participants should work through based on user requirements, and choose appropriate test measures. Use a test environment as close to the intended use environment as possible. This should also take into account whether users will have received training with a device prior to its use, as well as the availability and use of manuals in real world settings.

Participants

The number of participants used will depend on where in the development lifecycle the user testing is taking place. It may be beneficial to start by testing the product on two or three representative users, but more complete user studies will require at least 10 critical users. This

means including novice users to place the device design under most stress, and expert healthcare professional users to highlight problems associated with pre-existing habits. Include patient and carer populations if necessary.

Testing procedure

Test one user at a time, allowing at least half an hour for each person. They can be asked to attempt more than one scenario. Possible scenarios could include identifying details of an infusion being administered, identifying the current device status, and programming a new infusion.

The purpose of the user test is to determine if such common tasks can be carried out quickly, easily and without error. If errors do occur, they should be immediately detectable and easy to rectify. Objective measures could include time taken to complete each task, and number of errors or omissions. Subjective measures could include users' confidence that they have successfully completed the task and perceived ease of use and safety of device design.

When conducting the user test:

Observe and write down what the users do. If a user becomes confused, note how they deal with the difficulty.

If a user gets stuck with a task, avoid giving the answer. Instead, ask them what they would do in a real scenario.

Ask any questions that might extend the information gathered. Such questions could ask about the usability of a particular design element, or the clarity of the interface.

Results

Reviewing the data should reveal any major problems with the usability of the infusion device. The earlier in the design process the user testing is conducted, the greater the possibility for redesign before further testing.

Appendix 2: Advisory panel

A stakeholder review panel was formed to ensure this booklet addresses a wide and representative range of issues, across care settings and international boundaries.

Name	Role
Nick Abraham	Head of Clinical Engineering, Imperial College Healthcare NHS Trust
Emma Boakes	Human Factors Specialist, NPSA
Prof David Cousins	Head of Safe Medication Practice and Medical Specialties, NPSA
Craig Davey	Centre Manager, BIME Evaluation Laboratory
Beth Griffiths	Clinical Engineering, Nottingham University Hospitals NHS Trust
Mona Habib	Clinical Engineering, Imperial College Healthcare NHS Trust
Roger Jones	Clinical Engineering, Cardiff and Vale Hospital NHS Trust
Jim Lefever	Medicine and Healthcare products Regulatory Agency
Ed Matthews	Head of Design for Patient Safety, Helen Hamlyn Centre
Dr Beverley Norris	Human Factors Lead, NPSA
Michelle Sanderson	Equipment Library Manager, Newcastle upon Tyne Hospitals
Marina Stock	Clinical Engineering, Cardiff and Vale Hospital NHS Trust
Shakira Watts	ICU Nurse Educator, Imperial College Healthcare NHS Trust

References

1. National Patient Safety Agency. *Improving infusion device safety. Patient Safety Notice 01.* (2004). Available at: **www.nrls.npsa.nhs.uk/resources/?EntryId45=59788**

2. Anon. Infusion devices. Understanding the patients perspective in order to avoid errors. *Professional Nurse* 2003: 5-9

3. Medicines and Healthcare products Regulatory Agency. *Device Bulletin 2003 (02) 'Infusion Systems'.* (2003). Available at **www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON007321**

4. National Patient Safety Agency. *Evaluation report on standardising and centralising infusion devices – a project to develop solutions for NHS Trusts. Full evaluation report.* (2004). Available at: **www.nrls.npsa.nhs.uk/resources/?EntryId45=59788**

5. Quinn C, Stevenson E, Glenister H. NPSA Infusion device toolkit: a cost-saving way to improve patient safety. *Clinical Governance* 2004; 9: 195-199

6. Department of Health and Design Council. *Design for patient safety. A system wide design led approach to tackling safety in the NHS.* (2003). Available at: **www.edc.eng.cam.uk/medical/reports.html**

7. Shingo, S. *Mistake-proofing for operators: The ZQC System.* (1997).

8. Centre for Evidence-based Purchasing: **www.pasa.nhs.uk/pasaweb/NHSprocurement/CEP**

9. Bath Institute For Medical Engineering. Evaluation Centre: **www.bath.ac/bime/evalcentre**

10. Medicines and Healthcare products Regulatory Agency. Medical Device Alerts. Available at: **www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/index.htm**

11. Nemeth C, Nunnally M, Bitan Y, Nunnally S, Cook RI. Between choice and chance: the role of human factors in acute care equipment decisions. *J Patient Saf* 2009; 5: 114-21

12. Brixey JJ, Zhang J, Johnson TR, Turley JP. Legibility of a volumetric infusion pump in a shock trauma ICU. *Jt Comm J Qual Patient Saf* 2009; 35: 229-35

13. Protection against mechanical hazards, Section 4 BRITISH STANDARD BS EN 60601-1:1990, BS 5724-1: 1989

14. Stability in normal use, Section 24 BRITISH STANDARD BS EN 60601-1:1990, BS 5724-1: 1989

15. National Patient Safety Agency. *Patient Safety Alert 21. Safer practice with epidural injections and infusions.* (2007). Available at: **www.nrls.npsa.nhs.uk/resources/?EntryId45=59807**

16. National Patient Safety Agency. *Patient Safety Alert. Safer spinal (intrathecal), epidural and regional devices.* (2009). Available at: **www.nrls.npsa.nhs.uk/resources/?EntryId45=65259**

17. Liu L, Holescher U & Gruchmann T. Symbol Comprehension in Different Countries: Experience Gained from Medical Device Area in A.Auinger (Hrsg.): Workshops-Proceedings der 5 fachübergreifenden Konferenz Mensch und Computer Wien: Oesterriechische Computer Gesellschaft, 2005, S 81-87

18. IEC/TR 60878. Graphical symbols for electrical equipment for medical practice. Edition 2. International Electrotechnical Commision. Technical Report. 2003. Available at: **www.techstreet.com/standards**

19. ISO Standard 9186. Graphical symbols - Test methods for judged comprehensibility and for comprehension. International Standards Organisation 2001. Available at: **www.iso.org**

20. Colle & Hiszem. Standing at a kiosk: Effects of key size and spacing on touch screen numeric keypad performance and user preference. *Ergonomics* 2004; 47(13): 1406-1423

21. Jin ZX, Plocker T, Kiff L. Touch screen user interfaces for older adults: button size and spacing. Universal access in human computer interaction. *Coping with diversity* 2007; 4554: 933-941

22. Edworthy J & Hellier E. Alarms and human behaviour: implications for medical alarms, *British Journal of Anaesthesia* 2006; 97: 12-17

23. Department of Health. *Coding for Success.* (2007). Available at: **www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyandGuidance/DH_066082**

24. Food and Drugs Administration (USA). Name differentiation project. 2001. Available at: **www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm164587.htm**

25. Filik R et al. Drug name confusion: Evaluating the effectiveness of capital ('Tall Man') letters using eye movement data. *Social Science and Medicine,* 2004; 59: 2597-601

26. Quinn C. Infusion devices: understanding the patient perspective to avoid errors. *Prof Nurse* 2003; 19(2): 79-83

27. Food and Drugs Administration (USA). *Guidance for industry amd FDA premarket and design control reviewers. Medical device use-safety: Incorporating human factors engineering into risk management* (2000). Available at: **www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094461.pdf**

28. The Association For The Advancement Of Medical Instrumentation. Human factors design process for medical devices AAMI/AåNSI HE74:2001. Available at **www.techstreet.com**

29. International Electrotechnical Commission. IEC 6061-1-2. *Medical electrical equipment parts 1 -2. General requirements for basic safety and essential performance.* (2000). Available at: **http://webstore.iec.ch**

30. International Electrotechnical Commission IEC 62366. *Medical devices. Application of usability engineering to medical devices.* (2007). Available at: **www.iso.org**

31. Sawyer D. *Do It By Design: An Introduction to Human Factors in Medical Devices.* (1996). Available at: **www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm095061.pdf**

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